HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL

October 24, 2013

Food & Drug Administration (FDA)
Division of Small Manufacturers,
Consumer & Int'l Assistance (DSMICA)
Center for Devices & Radiological Health (CDRH)
Bldg. 66, Rm. 4621
10903 New Hampshire Ave.
Silver Spring, MD 20993

The Health Industry Business Communications Council (HIBCC) formally requests an application for accreditation as an Issuing Agency, as defined in the Food and Drug Administration's (FDA) final regulation for Unique Device Identification (UDI). (Docket No. FDA-2011-N-0090 / RIN No. 0910-AG31.)

HIBCC is an industry-sponsored and supported non-profit organization (501c6), founded in 1983 to develop a standard for unique identification of medical devices. We administer the Health Industry Bar Code Supplier Labeling Standard (HIBC SLS) designated in the final regulation as an accepted UDI format.

HIBCC is accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and is recognized by the International Organization for Standardization (ISO). Our efforts are supported worldwide by affiliate offices in Europe and Asia Pacific.

Should additional information be needed to process this request, please contact me at 602.381.1091 or via email at rhankin@hibcc.org.

Sincerely,

Robert A. Hankin

Robert A. Hankin, PhD.
President & CEO

Hawthorn, Anne T.

From: Hawthorn, Anne T.
Sent: Wednesday, October 30, 2013 4:29 PM
To: 'sjpolan@hibcc.org'
Subject: HIBCC's request for accreditation as an Issuing Agency for purposes of FDA's Unique Identification System

Sara

I am reviewing HIBCC's request for accreditation as an Issuing Agency for purposes of FDA's Unique Identification System requirements. Regrettably, there is information missing from your request. Please provide by emailing back to me a pdf that includes the following information.

1. Is your issuing agency a private organization?
2. Does your issuing agency's system employ UDIs that meet the requirements of 21 CFR 830.20 to adequately identify a device through its distribution and use?
3. Will your issuing agency make available information concerning its system for the assignment of UDIs?
4. Will your issuing agency maintain a list of labelers that use its system for the assignment of UDIs and be able to and provide FDA a copy of such list in electronic form by December 31 of each year?
5. Does your issuing agency's system conform to the following international standards?
    a. ISO/IEC 646:1991, Information technology—ISO 7-bit coded character set for information interchange;
    b. ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition, March 1, 2006);
    c. ISO/IEC 1549-4:2008, Information technology—Unique identifiers—Part 4: Individual items (second edition, July 7, 2008);
    d. ISO/IEC 1549-6:2007, Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition, June 15, 2007).
6. Does your issuing agency's system only use characters and numbers from the invariant character set of ISO/IEC 646?
7. Is your issuing agency's system available to all users according to a single set of consistent, fair, and reasonable terms and conditions?
8. Will your issuing agency protect against conflicts of interest between the issuing agency (and its officers, employees, and other agents) and labelers (and their officers, employees, and other agents) seeking to use UDIs that may impede the applicant's ability to independently operate a fair and neutral identifier system?

Please also include the following information, materials, and supporting documentation.

a. Name, address, and phone number of the applicant;

b. Detailed description of any standards or criteria the applicant will apply to the participating labelers; PLEASE ATTACH
c. Detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device PLEASE ATTACH
d. Detailed description of the review and decision-making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including:
    i. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system; PLEASE ATTACH
    ii. Policies and procedures for notifying a labeler of deficiencies in its use of UDIs; PLEASE ATTACH
    iii. Procedures for monitoring a labeler's correction of deficiencies in its use of UDIs; PLEASE ATTACH
    iv. Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process. PLEASE ATTACH
e. Description of the issuing agency's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems; PLEASE ATTACH
f. Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available; PLEASE ATTACH
g. Detailed information regarding any financial or other relationship between the applicant and any labelers or governmental entities; PLEASE ATTACH

Please contact me if you have any questions. If possible it would be helpful, although it is not required, to have the information as a single document, in the order listed above, with a table of contents.

Anne

Anne T. Hawthorn, JD
Regulatory Policy Analyst (detail)
OSB|CDRH|FDA
WO Bldg 66, Rm 3276
phone 301 796-6561

For more information on UDI and the UDI help desk see www.fda.gov/udi

HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL

Anne T. Hawthorn, JD
Regulatory Policy Analyst (detail)
OSB|CDRH|FDA
WO Bldg 66, Rm 3276

1. Is your issuing agency a private organization?

HIBCC is designated by the Internal Revenue Service as a 501(c)6 non-profit corporation (Federal EIN 36-3313052.) HIBCC is accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and is recognized by the International Organization for Standardization (ISO).

2. Does your issuing agency's system employ UDIs that meet the requirements of 21 CFR 830.20 to adequately identify a device through its distribution and use?

Yes. The Health Industry Bar Code Supplier Labeling Standard (HIBC SLS) is that system (attached). It provides a standardized structure for creating all of the elements required by the UDI regulation for developing device identifiers and production identifiers.

3. Will your issuing agency make available information concerning its system for the assignment of UDIs?

Yes. We have created an online UDI Resource Center at www.hibcc.org which contains all the necessary documentation and guidelines related to UDI assignment. In addition, we have made available a 'UDI Generator' utility which allows labelers to input their data and create both a device identifier and a production identifier, or in some cases use it confirm their own calculations.

4. Will your issuing agency maintain a list of labelers that use its system for the assignment of UDIs and be able to and provide FDA a copy of such list in electronic form by December 31 of each year?

Yes. This list will be provided electronically to the FDA by December 31 of each year. It is also available to the public on our web site in various electronic formats, and is updated as new labelers register. HIBCC has long made this available to the public as a resource.

5. Does your issuing agency's system conform to the following international standards?

ISO/IEC 646:1991, Information technology—ISO 7-bit coded character set for information interchange;
Yes.

ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition, March 1, 2006);
Yes.

ISO/IEC 1549-4:2008, Information technology—Unique identifiers—Part 4: Individual items (second edition, July 7, 2008);
Yes.

ISO/IEC 1549-6:2007, Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition, June 15, 2007).
Yes.

6. Does your issuing agency's system only use characters and numbers from the invariant character set of ISO/IEC 646?
Yes.

7. Is your issuing agency's system available to all users according to a single set of consistent, fair, and reasonable terms and conditions?

Yes. HIBCC standards are developed in accordance with the strict guidelines of the American National Standards Institute (ANSI), so that the system is consistent and open to the public. There are no restrictions on who can use the standards.

8. Will your issuing agency protect against conflicts of interest between the issuing agency (and its officers, employees, and other agents) and labelers (and their officers, employees, and other agents) seeking to use UDIs that may impede the applicant's ability to independently operate a fair and neutral identifier system?

Yes. As part of the ANSI processes, all standards work is open to the public for comment so that the system remains fair and balanced. This year HIBCC successfully completed an ANSI audit of our organization and standards development processes. (A copy of the ANSI re-accreditation letter is attached.)

a. Name, address, and phone number of the applicant;
Health Industry Business Communications Council (HIBCC)
2525 E Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016
P: 602.381.1091 E:info@hibcc.org W:www.hibcc.org

b. Detailed description of any standards or criteria the applicant will apply to the participating labelers;

HIBCC's Supplier Labeling Standard (SLS) is accredited by ANSI, and in conformance with the FDA UDI regulation. Labelers using the HIBC SLS are required to strictly adhere to the standard in order to be in conformance with the UDI regulation from which they will derive their device and production identifiers. In order to become a labeler, the interested party will register with HIBCC to obtain a Labeler Identification Code (LIC). HIBCC will then assign a unique 4-digit, alphanumeric code (such as M123) to identify the registrant. The LIC code is never duplicated or reassigned and thus is distinctly unique to that registrant/labeler. HIBCC maintains the LIC assignments in an internal database.

c. Detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device.

The HIBC Supplier Labeling Standard (SLS) is the guideline from which a labeler will derive their UDI data. The HIBC SLS specifies the type of information that should be encoded and the method of doing so.

For instance, the primary data string requires a "+" flag character, the 4-character LIC, a 1-18 character product or catalog identifier, a one-digit unit of measure and a single-digit. Elements of this data string become the device identifier.

Secondary information such as lot/batch number, serial number, expiry date and date of manufacture are prescribed as well, and will provide the method for developing the production identifier. (Please reference the attached HIBC SLS for specific encoding requirements.)

Because the LIC assignment is unique to the individual labeler and never reassigned to a different labeler, when attached to their own product code it inherently creates a unique data string. No two UDIs could be alike because of the uniqueness of the LIC assignment. And because the HIBC SLS is variable length, and alphanumeric there are virtually limitless numbers of possible FDA-compliant UDIs.

d. Detailed description of the review and decision-making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including:

The HIBCC UDI is an open standard and available to all parties that elect to use it.

The HIBCC organization is the sole assigner of the Labeler Identification Code (LIC). An application form and payment of a one-time fee is required for assignment of an LIC. This is discussed in more detail in section "F".

e. Description of the issuing agency's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

HIBCC currently maintains numerous databases for the health care industry and routinely distributes the data via various mediums including hard format, Electronic Data Interchange (EDI) and web-based services. These data distribution processes occur daily, weekly and quarterly. As such HIBCC is well positioned in terms of experience and infrastructure to provide electronic data in a format compatible with FDA data systems.

The draft guidance on the Global Unique Device Identification Database (GUDID) is currently being reviewed by HIBCC so that it can plan for the development of FDA-compatible systems when the final specification is released.

f. Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available;

HIBCC has been registering labelers for 30 years, and will further enhance processes to meet UDI requirements. The registration process requires a new labeler to pay a one-time application to HIBCC for assignment of the Labeler Identification Code (LIC). Thereafter, there are no reoccurring fees to the labeler to maintain their LIC. HIBCC continues to provide technical support and guidance to labelers at their request. The assigned LIC is applied globally, and can be used for the labeling of a registrant's entire product line.

There are no fees for individual product code assignments. Additionally, because of the variable-length, alphanumeric structure of the HIBC Supplier Labeling Standard, there are virtually limitless possible combinations to create a UDI compliant data string.

The LIC registration fee is based upon a progressive fee-schedule that is tied the labelers gross annual sales in its immediate prior fiscal year. LIC registration fees are extremely modest and because of their progressive schedule to do not impose a burden on small companies. We estimate that the vast majority of the medium to large companies already have a HIBC LIC or GTIN, therefore we believe the majority of new applicants will be at low-end of the fee schedule. (Application and fee schedule are attached.)

g. Detailed information regarding any financial or other relationship between the applicant and any labelers or governmental entities;

HIBCC provides fee-based database services to companies utilizing our Health Industry Number (HIN) System customer identifier. In some cases, those companies may also be labelers, however it does not relate to the UDI system or our LIC application process.

The volunteer HIBCC Board of Directors is comprised of individuals representing various companies that are part of the healthcare supply chain, and can also include the appointment of a government representative. These individuals are typically appointed by various trade organizations active in the industry. Volunteers are not compensated by HIBCC, nor are they reimbursed for expenses. The role of the Board is to guide the development of the HIBCC organization to meet the evolving needs of the industry we serve.

HIBCC POLICIES & PROCEDURES FOR UDI COMPLIANCE

As of September 15th, 2013

HIBCC is implementing a three-pronged approach to assist labelers with conformance to the HIBC Supplier Labeling Standard (HIBC SLS), and compliance with FDA's UDI Regulation. Through a variety of programs and resources, HIBCC will provide (1) Education, (2) Certification, and (3) Review.

Education

- The UDI Resource Center, available at www.hibcc.org, was developed to be a central resource for UDI reference materials. Guidelines, applications and instructional documents are provided, as well the on-line "UDI Generator" utility that allows a labeler to enter their data and be provided with an FDA-compliant UDI.

- UDI compliance webinars and meetings will be offered through online functions and in scheduled UDI User Group sessions. HIBCC will partner with labelers, vendors of auto-identification products and regulators to develop guidelines for compliance education.

Certification

- New labelers are asked to certify in the LIC application that they agree to be in conformance with the HIBC SLS structure so that they may derive FDA compliant UDI's.

- New labelers will be asked to submit sample UDI data to HIBCC, where it will be scanned and verified. In the event of a non-compliant UDI, HIBCC will advise the labeler of the error and request corrective action be taken, and a revised UDI be re-submitted.

- In the event of the labelers continued non-compliance, they will be notified and given a reasonable time period in which to correct the issues and resubmit data.

- If the non-compliance is not addressed after that time period, the labeler will be notified that their LIC assignment is suspended. FDA will be notified, as warranted.

- In the event that HIBCC is providing GUDID data-transfer services for the labeler, incorrect data will not be submitted to FDA and returned to the labeler for corrective action.

Review

- HIBCC will query all LIC registrants on an annual basis to maintain the currency of contact information in the LIC database.

- HIBCC prohibits the transfer of LICs to other companies or organizations (for example, due to changes in ownership, merger etc.) without prior written notification to HIBCC. A labeler is required to notify HIBCC of the change and reregister in order to update the LIC database accordingly.

Health Industry Business Communications Council

Registered Labelers: Accredited Auto-ID Labeling Standards

The following companies (and/or their subsidiaries/ divisions) have applied for a Labeler Identification Code (LIC) assignment with HIBCC or one of our international affiliates. By doing so, they have demonstrated their commitment to patient safety and logistical efficiency for their customers, the industry and the public at large.

Any organization that is interested in using the HIBC uniform labeling system may apply for the assignment of one or more LICs.

Last updated 10-30-2013

Austria

AMI GmbH
Bender Medsystems GmbH
PAA Laboratories GmbH
W & H Dentalwerk Burmoos GmbH

Australia

Adv. Surgical Design & Manufacture, Ltd.
Bioclone Australia Pty. Ltd.
DePuy Australia Pty. Ltd.
H Trak Pty Ltd
Med.& Surg. Requisites Pty. Ltd.
Medigroup Australia Pty. Ltd
Opto Global Pty. Ltd.
Signostics Ltd.
Sirtex Medical, Ltd.
Smith & Nephew Surgical Pty. Ltd.
The Pipette Company Pty. Ltd.
Thermo Electron Corporation
William A Cook Australia Pty. Ltd.

Belgium

3M Europe
Advanced Medical Diagnostics SA/NV
Analis SA/NV
Baxter World Trade
Bio-Rad RSL
  Bio-Rad Lab Inc Clinical Diag. Group
Biosource Europe SA
Cilag NV
Coris Bioconcept
Fuji Hunt Photographic Chemicals NV
GC Europe N.V.
Int'l Pharmaceutical Services BVBA
Johnson & Johnson International
  Medical Products
Materalise NV
Mayne Pharma
Molnlycke Europe SA
Orange Scientific SA
Pierre Fabre Benelux
Scimed Europe S.P.R.I.
Théa Pharma SA

Brazil

Biolab Diagnostica SA
Johnson & Johnson Prod. Prof. LTDA
Labcor Laboratorios Ltda.

Canada

Baylis Medical Company, Inc.
Beavers Dental
  Sybron Dental Specialties
Bio-Dent
CardioMed Supplies
ECI Medical Technologies, Inc.
ID Labs, Inc.
Johnson & Johnson, Inc.
  Iolab Canada, Inc.
  Janssen Pharmaceutica, Inc.
  Johnson & Johnson Med. Prod.
  Ortho Diagnostic Systems, Inc.
  Ortho Pharmaceutical Corp.
Mespere LifeSciences Inc.
Mitroflow, Inc.
Numed Canada, Inc.
Oculo-Plastik, Inc.
O-Two-Systems International
Pinel Medical, Inc.
Primed Instruments, Inc.
Primeline Medical Products, Inc.
Prodrive Systems, Inc.
QXMedical, LLC

For more information, please contact the HIBCC office at:

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
TEL: 602.381.1091
FAX: 602.381.1093
info@hibcc.org
www.hibcc.org

Span Medical Products Canada Inc.
MC Healthcare Products
Stryker Corporation
Stryker Bertec
Synergy Disc Replacement, Inc.
The Canadian Red Cross Society
The Westaim Corporation
Nucryst Pharmaceuticals
Vivosonic, Inc.
Wisent, Inc.
Zimmer, Inc.
Zimmer CAS
Zimmer Manufacturing BV
Zimmer Orthopedics Mfg. Ltd.

China (includes Hong Kong)

Ming Industries Limited
Stryker Corporation
Stryker Suzhou

Czech Republic

Spofadental SA

Denmark

Coloplast A/S
Contura International A/S
Radiometer Medical A/S
Virogates A/S
William Cook Europe A/S

Finland

Bioretec, Ltd.
Helsinki University Central Hospital
Inion, Ltd.
Kolmi-Set OY
Linvatec Biomaterials, Ltd.
LM - Instruments OY
Mediala OY
Orgenium Laboratories
Oy Fluorplast AB
Sataside OY
Stick Tech Ltd
Tyke OY

France

Amplitude
ARTHRO-DIF
ATF-Vitatech
Becton Dickinson France SA
Biomatlante
BioMérieux BV
BioMérieux SA
C2F-Implants
CFPM
Dedienne Sante
Denstply France SAS
DePuy Bioland
DePuy France
Endo Control
Ethicon Ethnor SAS
Eurospine Sarl
Evolutis SAS
FFDM Pneumat
Graftys - Sarl
Groupe Lepine
Helioscopie-Ceerdil
Hesperis
Hexacath Sarl
Implants Serv. Orthopediques (Iso-Ortho)
Intervascular Sas
Ioltech Laboratoires
Itena-Clinical
Johnson & Johnson Medical Sarl
Kasios
LDR Medical
Lisi Medical Orthopaedics
Medicoscop
Medicrea
Memometal Technologies
Micro-Mega SA
Neosteo
Newdeal
Obvieline
Pierre Rolland
Protheos Industrie
Quetin SA
Sarl Biomatlante
Satelec (Acteon Group)
Sedat
Serf
SGM
Sofradim Production
Sopro
Surfix
Theraclion SA
Thiebaud Biomedical Devices
Tornier SA
Vexim
Vitalitec International

Germany (Deutschland)

3M ESPE AG
A. Schweikhardt GmbH & Co. KG
AAP Biomaterials GmbH
AAP Implantate AG
Abbott Vascular Instruments De. GmbH
Acandis GmbH & Co KG
AD GmbH
Adamus GmbH
Adentatec GmbH
Adeor Medical Technologies GmbH
Aesculap AG
Aesculap AG & Co. KG
AJ Roboscreen GmbH
Alpro Dental Produkte GmbH
Altatec GmbH
Amann Girrbach GmbH
ANM Adaptive Neuromodulation GmbH
Applichem GmbH
AristoTech Implant Technologies GmbH
Artoss GmbH
Asanus Medizintechnik GmbH
Auritec Medizindiagnotische Syst. GmbH
B Braun Melsungen AG
Bandelin Electronic GmbH & Co KG
BEGO GmbH & Co
BEGO Implant Systems GmbH & Co. KG
BEGO Medical AG
BEGO Semados GmbH
Beiersdorf AG Inc.
Berchtold Holding GmbH
Bernhard Förster GmbH
Bess Pro GmbH
Biocam GmbH
Biocer Entwicklungs GmbH
Biocheck GmbH
Bio-Rad Laboratories GmbH
Bio-Rad Lab Inc Clinical Diag. Group
Bio-Rad Medical Dianostics GmbH
Biotest AG
Bluepoint Medical GmbH & Co. KG
Bosch + Sohn GmbH U. Co KG
Bredent Medical GmbH & Co. KG
Carl Teufel GmbH & Co. KG

Registered Labelers

Carl Zeiss Surgical GmbH
Coltène/Whaledent GmbH & Co. KG
Croma GmbH
DeguDent GmbH
Degussa AG
Dentaurum GmbH & Co. KG
Dentaurum J P Winkelstroeter KG
Dentrade E.K.
Dentsply GmbH
DePuy Orthopadie Gmbh
Detax GmbH & Co. KG
Devemed GmbH
Devon Medical GmbH
Diasorin Deutschland GmbH
DMG
Dr. Fenning - BioMed GmbH
Dr. Hopf GmbH & Co. KG
Dr. Hopf, Ringleb & Co. GmbH
Dr. Ihde Dental AG
Dr. Jean Bausch KG
Dr. Schmidt Intraocularlinsen GmbH
Dreve
DRS International GmbH
Dufner Instrumente GmbH
Durr Dental AG
E. Hahnenkratt GmbH
ED GmbH
Einfeldt
Eisenbacher Dentalwaren ED GmbH
Elmicron
Emil Lange Zähnbohrerfabrik E.K.
Esprident GmbH
Ethicon GmbH
Eucatech AG
Eukamed E.K.
Eve Ernst Vetter GmbH
Favodent Karl Huber GmbH
Fischer Analysen Instrumente GmbH
Fotochemische Werke GmbH
Friadent GmbH
G. Heinemann Medizintechnik GmbH
GEBDI Dental-Products GmbH
Gebr. Brasseler GmbH & Co. KG
Gebruder Martin GmbH & Co. KG
Geister Medizintechnik.De
Genzyme Virotech GmbH
GKE GmbH
Greiner Bio-One GmbH
Greiner Bio-One GmbH (Austria
Greiner Bio-One GmbH (Hungary)
Hager & Meisinger
Hager & Werken GmbH & Co.KG
Harvard Dental International GmbH
HEBU Medical GmbH
Hedent GmbH Dentalgeräte U. Materialien
Heimerle+Meule GmbH
Heine Optotechnik GmbH & Co KG
Heinz Kurz GmbH Medizintechniek
Helmut Zepf Medizintechnik GmbH
Heraeus Kulzer GmbH
Hermann Medizintechnik GmbH
Hint-Els GmbH
Horcher GmbH
IBA Dosimetry GmbH
Implantcast GmbH
Inomed Medizintechnik GmbH
Jakoubek Medizintechnik GmbH
Johnson & Johnson Medical GmbH
Kallmeyer Medizintechnik GmbH
Kaltenbach & Voigt
Kaniedenta
Karl Berg GmbH
Karl Storz - Endoskope
KaWeCo Gmbh - Kimetec GmbH
Kentzler-Kaschner Dental GmbH
Kettenbach GmbH & Co. KG
Kimetec Medizintechnik GmbH
Kohler Medizintechnik GmbH
Lawton GmbH & Co. KG
Leoni Fiber Optic GmbH
Lohmann Gmbh & Co. KG
M&W Dental
Medentika GmbH
Medicoplast International GmbH
Medi-Globe
Medisys GmbH
Mediwiss Analytic GmbH
Mednet GmbH
QCORE
Megadenta Dentalproduckte GmbH
Merz & Co. GmbH
Merz Dental GmbH
Metrax GmbH
Meyer-Haake GmbH Medical Innovations
MGB Endoskopische Gerate GmbH Berlin
MIPM Mammendorfer Institut GmbH
Mitsubishi Pharma Deutschland GmbH
Moller-Wedel GmbH
Müller-Omicron GmbH & Co. KG
Noba-Verbandmittel
Normed Medizin-Technik GmbH
Novatec Immundiagnostika GmbH
NTI-Kahla GmbH
OHST Medizintechnik.De
Okodent Preusser OHG
Omnident GmbH
Orbis Dental
Orochemie Durr & Pflug GmbH & Co. KG
Osmed GmbH
OT Medical GmbH
Pioneer Medical Devices AG
Polytech Ophtalmologie GmbH
PRO-MED Instrumente GmbH
Protec GmbH & Co. KG
Prowital Dental Implants GmbH
PTW-Freiburg
PVB Medizintechnik GmbH
QIAGEN GmbH
Reitel Feinwerktechnik GmbH
Renfert GmbH
Resorba
Richard Wolf GmbH
RoweMed AG
Sartorius Stedim Plastics GmbH
Scheu-Dental
Schutz Dental GmbH
Serag-Wiessner KG
Signus Medizintechnik GmbH
Sirona Dental Systems GmbH
Sopro-Comeg GmbH
Speiko - R. Speier GmbH
Spiggle & Theis Medizintechnik GmbH
Stericop GmbH & Co.KG
Steristics AG
Storz Am Mark GmbH
Stryker Leibinger GmbH & Co. KG
Stryker Trauma GmbH
Sutter Medizintechnik GmbH
Sybron Implant Solutions GmbH
Transatl. Handels-Ges. Stolpe &Co. GmbH
Trumpf Medizin Systeme GmbH
Tut-Instruments GmbH

Ulrich Storz GmbH & Co. KG
Universitatsklinikum Bonn
Urotech Medizinische Technologie Gmb
Valmex Photographische Produkte GmbH
Vanguard A.G.
VDW GmbH
Vims Sas
Viramed Biotech AG
Vita Zahnfabrik
Voco GmbH
Völker AG
Wagner GmbH
Wassermann Dental-Maschinen
Wavelight GmbH
Welch Allyn GmbH & Co. KG
WhiteSmile GmbH
Willmann & Pein GmbH
Xion GmbH
Yeti Dentalprodukte GmbH
Zhermack GmbH Deutschland
Zimmer Medizin Systeme GmbH
ZL-Microdent Attachment GmbH & Co.KG

Hungary

Medimetal, Ltd.
Sanatmetal

India

Aaropna Protesi Private Limited
Ethicon Div. of Johnson & Johnson, Ltd.

Ireland

Abbott Ireland, Ltd.
Abbott Vascular Devices
Allergan, Inc.
Astellas Ireland Co., Ltd
Creagh Medical Ltd.
Howmedica Int'l., Inc.
Johnson & Johnson Professional, Ltd.
Mednova
Proxy Biomedical, Ltd.
Stryker Ireland (Cork)
Stryker Orthopaedics
Takumi Medical
X-Bolt Orthopaedics

Israel

Etview
Medinol, Ltd.
MIS Implants Technologies, Ltd.
OHK Medical Devices, Ltd.
Q Core Medical
T.A.G. Medical Products Corporation, Ltd.
Virtual Ports, Ltd.

Italy

AB Medica SPA
Adaltis SRL
ALA Ortho SRL
ASA Dental SPA
Bioengineering Laboratories SPA
Biotek SRL
Blue X Imaging SRL
Cominox SRL
Copan Flock Technologies SRL
Copan Italia SPA
Critikon-Johnson & Johnson Prof. Prod.
Dia. Pro Diagnostic Bioprobes SRL
Diasorin SPA
Dideco SPA
Ethicon SPA Italy
Euronda SPA
Fidia Pharma USA Inc.
Gambro SPA
Hofmann SRL
IGEA SRL
Intrauma SRL
Johnson & Johnson Medical Holding SPA
Kerr Italia SPA
Lima-LTO SPA
M.O. Com SRL
Mauritius SRL
MD & I SRL
Mectron SPA
Medical Plastic SRL
MIR Medical International Research
NGC Medical SPA
Novater SRL Unipersonale
O.M.S. SPA
Optikon 2000 SPA
Q.R Srl
Rand SRL
RS Medica SRL
Sclavo Diagnostics International SRL
Sentinel CH. SPA
Sintea Biotech SPA
Sire Analytical Systems
Alifax SPA
Sorin Biomedica Cardio SPA
Tecno-Gaz SPA
W&H Sterilization SRL

Japan

Asicon Tokyo, Ltd.
Fuji Photo Film Co., Ltd.
GC Corporation
Konica Corporation
Kuraray Medical, Inc.

Liechtenstein

Inovis Vivadent AG
Ivoclar Vivadent AG
Kenda AG
SDS Swiss Dental Solutions

Malaysia

Careplus (M) SDN. BHD.

Mexico

Mallinckrodt Medical, Inc,
Mallinckrodt Medical TPI, Inc.

The Netherlands

Abbott BV
Abott Products BV/Solvay Pharma BV
Academisch ZKH. Maastricht
Actavis BV
Actelion Benelux
Added Pharma
AHP Pharma BV
Albic BV
Alcon Pharmaceutical, Ltd.
Allgen Pharmaceuticals & Generics
Alliance Health Care
Amgen Europe BV
Astellas Farma Europe BV
Astra Pharmaceutical Products, Inc.
Astra Zeneca BV
B V Euromedica
Basic Pharma Mfg. BV
Basiq Dental BV

Registered Labelers

Bayer BV
Biomet Nederland BV
Bipharma BV
Blue Medical Devices BV
Boehringer Ingelheim BV
Boots Pharma./Healthcare BV
Bournonville-Pharma BV
Brocacef BV
Brocacef Intramuraal BV
Bufa - Chemie BV
Byk Nederland BV
Catharina Ziekenhuis
Cavex Holland BV
Centrafarm BV
Central Lab VD Bloedtransfusiedienst
Chiron BV
Christelijke Vereniging Het Diaconessenhuis Leiden
Christiaens BV
Clinimed Holding BV
Confedera BV
CSL Behring BV
De Koningh Coding & Packaging
Delphi Pharmaceuticals BV
DG Lederle Nederland BV
Disphar International BV
Dowelhurst Netherlands BV
Dr. Coenraad Consortium CV
Dumex BV
Duphar Nederland BV
E Merck Nederland BV
Elana
Elephant Dental BV
Eli Lilly Nederland BV
EU-Pharma BV
Eureco-Pharma BV
Eurobase BV
Eurocept Pharmaceuticals
Extrapharm
E-Z-EM Nederland BV
Fagron Farmaceauticals BV
Fagron Services BV
Farmaceutische Ond. Lansberg-Rotterdam
Ferring B.V.
Fisher Farma
Fisons Pharmaceuticals
Fresenius BV
FRG Farma BV
Galderma SA
Genfarma
GenRx
Genthon BV
Getronics
Gist Brocades
GlaxoSmithKline BV
Grapharma BV
Grünenthal BV
Guerbet Nederland BV
Handelsonderneming Tempus BV
Hexal BV
Hoechst-Holland NV
Holland Pharmaceutical Supply BV
Homeoropa BV
ICI-Farma
Inpharzam/Zambon Nederland BV
Interpharm BV
Ipsen Farmaceutica BV
Jansen TMI BV
Janssen-Cilag BV
Janssen Pharamceutica BV
Johnson & Johnson Medical BV
Kabi Pharmacia BV
Karib Limited
Katwijk Farma BV
KNMP
Knoll BV
Koninklijke Utermohlen NV
Kring-Apotheek BV
Laboratorium Almirall Prodesfarma
LAGAP BNL BV
Leids Universitair Medisch Centrum
Leo Pharma BV
Leyden Delta BV
Lilly Nederland BV
Lorex Synthelabo BV
Lundbeck BV
Magnafarma BV
Maastricht
McNeil BV
Mecomfa BV
Meda Pharma BV
Medcor Pharmaceuticals BV
MEDECO BV
Medical NV
Medicopharma NV
Medport BV
Menarini Benelux NV
Mentor Medical Systems BV
Merck BV
Merck Generics BV
Merck Sharp & Dohme BV
Merops Pharma BV
MSD
Multipharma
N.V.I
Nedcox Pharma BV
Neopharm BV
New Neopharm BV
Nordic Pharma BV
Norgine BV
Novartis Consumer Health
Novartis Pharma BV
Novo Nordisk Farma BV
NPBI International BV
Nycomed BV
Occam International BV
Onderlinge Pharm Groothandel UA
OPG Groep NV
Ophtec BV
Ortomed BV
Parke-Davis BV Warner Lambert
PCH Pharmachemie BV
Pfizer BV
Pharbil
Pharbita BV
Phardis BV
Phareur BV
Pharmachemie BV
Pharmacia Upjohn BV
Pharmacin International BV
Pharmagent
Polyfarma BV
Prosan International BV
Ratiopharm BV
Reckitt Benckiser Healthcare
Rhone-Poulenc Rorer/Pharbil
Roche Nederland BV
Rooster & ZN. BV
Samenwerkende Apothekers Ned. BV
Sandoz BV

Sankyo Pharma Nederland BV

Sanofi Aventis
- Sanofi Aventis Nederland BV
- Sanofi Winthrop,
- Bristol Myers Squibb VOF

Sanquin

Schering-Plough Nederland BV

Searle Nederland BV

Sigma Tau Ethifarma BV

Sigma Tau Healthscience Int'l. BV

SmithKline Beecham Farma

Spruyt Hillen BV

St. Volksgez en Milieuhygiene

Stephar BV

Stephim BV

Stichting Registratie Beheer (SANDOZ)

Stichting Ziekenhuis Leyenburg

Syntex BV

Synthon BV

Taxandria Pharmaceitica BV

Technomed Europe BV

Tempus BV

Terapharm BV

Tio Farma

Tramedico BV

Trendpharma BV

UCB Pharma B V

United Pharma Group BV

Ursapharm Benelux BV

Valeant Pharmaceuticals International

Van Den Berg Nederland BV

Van Heek Meander BV

Viatris Manufacturing BV

ViiV Health Care

Wellcome Pharmaceuticals BV

Wyeth Laboratoria BV

Wyeth Pharmaceuticals BV

Yew Tree Pharmaceuticals

Zambon Nederland BV

Zyma-Nederland BV

Norway

Nycomed Imaging AS

New Zealand

Enztec Limited

Portugal

Johnson & Johnson Produtos Profissionals

Slovakia

Apothecon BV (0183)

Bristol-Myers Squibb BV

South Africa

Diasorin South Africa Pty. Ltd.

Johnson & Johnson Medical Prof. Prod.

Ortho Sol Pty. Ltd.

South Korea

Neobiotech Co., Ltd.

U&I Corporation

Spain

Howmedica Faimon SA

Howmedica-Iberica SA

Johnson & Johnson Prod. Prof.

Metalor Iberica

Sweden

AB Ardent

Carmel Pharma AB

Hospal - Gambro Renal Products

LIC Hygien AB

Medscand Medical AB

Molnlycke Health Care AB

Nobelpharma AB

Nordiska Dental AB

ScandiCare Products AB

Swemac Innovation AB

Switzerland

Assut Medical Sarl

Bien-Air SA

Biotronik AG

Candulor AG

Cendres & Métaux SA

Central Labs Blood Transfusion SVCS

Coltène AG

Degradable Solutions AG

Dentsply, Ltd.

Edenta AG

EMS-Electro Medical System SA

Endosense SA

Hamilton Medical AG

Hospal, Ltd.

Institut Straumann AG

JOTA AG

Kerrhawe SA

Maillefer Instruments SA

Medacta International SA

Metalor Technologies SA
- Division UGDO

Nouvag AG

Oro Clean Chemie AG

Polydentia SA

Precimed SA

Primequal SA

Prodonta SA

Produits Dentaires SA

Regen Lab SA

Rodent AG

Schiller AG

Schneider (Europe) AG

SIC invent AG

Stryker Trauma SA (Jaquet)

Tip Top Tips Sarl

Unor AG

Valtronic SA

Zimmer, Inc.
- Zimmer GmbH

Turkey

Altera Tibbi Malzeme San. Ve Tic. A.S.

United Kingdom

ABenge Advanced Biotechnologies, Ltd.

B Braun Meslungen AG

Biocomposites, Ltd.

Bio-Rad Laboratories Deeside, Ltd.

Bio-Rad Lab Inc. Clinical Diag. Group

Bridgemaster Medical, Ltd.

Corin, Ltd.

Critikon - Johnson & Johnson Prof. Prod.

Davis Schottlander & Davis, Ltd.

Dentsply International, Inc.
- Ash Instruments Dentsply
- C M W Laboratories
- Detrey Dentsply, Ltd.
- Medical & Industrial Equipment

DePuy International, Ltd.
- DePuy CMW

De-Soutter Medical, Ltd.

Ethicon Ltd. United Kingdom

E-Z-EM Limited

Finsbury Orthopaedics Limited

Future Spine Technologies Ltd.

Goldshield Group plc

Grant Instruments (Cambridge), Ltd.

Howmedica (Uk) Limited

Hyaltech, Ltd.

Iolab Intraocular

IVAX Pharmaceuticals UK

J & J Medical Ltd. UK

J & J Ortho Clinical Diag - Wales

Johnson & Johnson Orthopaedics Ltd

Johnson & Johnson Prod.Prof. Ltda.

Lidco, Ltd.

Lloyds TSB Registrars / BOC Health Care

Metalor Dental Products, Ltd.

Mitsubishi Pharma Europe, Ltd.

Myconostica, Ltd.

Neoligaments, Ltd.

Orthodynamics

Ortho-Trauma International LLP

Plasma Surgical Investments
  Plasma Surgical, Ltd.

Portex, Ltd.

Poulten & Graf, Ltd.

Ranbaxy UK, Ltd.

Ranier Technology Ltd.

Regent Hospital Products, Ltd.
  LRC Products, Ltd.

ScanTrack Healthcare Systems, Ltd.

Sherwood Medical Int.

Smith & Nephew Healthcare, Ltd.

Smiths Industries

Stanmore Implants Worldwide, Ltd.
  SIW Holdings, Ltd.

Stryker Howmedica Osteonics

Sulzer Vascutek, Ltd.

Summit Medical, Ltd.

Surgicraft (Mandaco 569) Ltd.

Synthes

Technical & General Ltd.

The Dental Directory,
  Billericay Dental Sup. Co.

Thermo Fisher Scientific

Tissue Science Laboratories PLC

Vadin Implants, Ltd.

United States

3M
  3M Imaging
  3M Med\Surg
  3M Orthopedic
  3M Pharm
  3M Vision Care

A Plus International

Aalto Scientific, Ltd.
  Audit Microcontrols, Inc.

Aaron Medical Industries, Inc.
  Bovie Medical
  Omniflex

Aastrom Biosciences

Abbott Laboratories
  Abbott Critical Care
  Abbott Diagnostic
  Abbott Hospital Production
  Abbott Pharma. Production
  Perclose, Inc.

Abco Dealers, Inc.

Ability One Corporation

Absorbent Products Company, Inc.

Access Closure, Inc.

Acclarent, Inc.

Accuray Inc.

Accuvein, LLC

ACell, Inc.

Acme United Corporation

ACMI

Acumed, Inc.

Addition Technology, Inc.

A-Dec, Inc.

Adhezion Biomedical, LLC

Adroit Medical Systems

Ad-Tech Medical Instrument Corporation

Advan Dx, Inc.

Advance Medical Designs, Inc.

Advanced Biomaterial Systems

Advanced Bionics LLC

Advanced Circulatory Systems, Inc.

Advanced Medical Optics

Advanced Meditech International, Inc.

Advanced Orthopaedic Solutions, Inc.

Advanced Vision Science

Aesculap Instruments Corp.

AFP Imaging Corporation
  Dent-X Corporation

AGA Medical Corporation

AGFA Corporation
  Matrix Division
  AGFA Healthcare

Air Techniques, Inc.
  All Pro Imaging
  Jelrus International

Airsep Corporation

Alba -Waldensian, Inc.
  Alba-Waldensian Health Prod. Div.

Alcide Corporation

Alcon Laboratories
  Pharmaceuticals

Alere San Diego Inc dba Biosite, Inc.

Allergan, Inc.

Alliance Spine, LLC

Alliant Enterprises, LLC
  Alliant Healthcare Products

Allo Source

Alpha Medical Instruments, LLC

Alpha-Tec Systems, Inc.

Alto Development Corporation
  A & E Medical Corporation

AMCOL International
  Chemdal Corporation

Amedica/US Spine

American Australian Medical

American Cyanamid
  Davis & Geck

American Dental Cooperative

American Dental Supply, Inc.

American Health Products Corp.
  Quinton Instrument Company

American Home Products Corp.
  Argyle Division of Sherwood
  Dover Urologicals Div.
  Monoject Div. of Sherwood Medical
  Oxford Chemistries Div.
  Oxford Lab Supplies Div.
  Oxford Liquid Handling Div.
  Sherwood, Davis & Geck
  US Clinical Products
  Veterinary Div. of Sherwood
  Wyeth-Ayerst Laboratories

American Sterilizer Company

Amerisource Bergen

Amersham Health/GE

Amerx Health Care Corp.

Amsino International, Inc.

Anatomical Concepts, Inc.

Anesthesia Medical Specialties, Inc.

Angeion Corporation

Angiodynamics
  E-Z-EM, Inc.

Angioguard, Inc.

Angioscore Inc.

Angiotech

Registered Labelers

Angiotech Biocoatings Corp.
Angiotech Pharmaceuticals, Inc.

Anika Therapeutics, Inc.

Anmuth Medical International

Ansell Healthcare Products LLC

Apogent Technologies
Erie Scientific Co.
Nalge Nunc Co.
Nerl Diagnostics Corp.
Richard Allan Scientific

Apotheus Laboratories, Ltd.
Scott Laboratories, Ltd.

Applied Medical Resources

Applied Spine Technologies

Argon Medical Devices, Inc.

Armour Pharmaceutical Company
USV Lab. Div. Pharma Corp.

Arrow International, Inc.
Precision Products

Arstasis, Inc.

Arteriocyte Medical Systems, Inc.

Arthrex, Inc.

Arthrosurface, Inc.

Arthrotek

Aspen Surgical Products, Inc.

Astra USA

Asuragen, Inc.

Athena Champion

Ati Orion

Atlas Spine, Inc.

Atricure, Inc.

Atritech, Inc.

Atrium Medical Corp.

ATS Medical, Inc.

Auric Enterprises, Inc.
Diack

Austenal Dental, Inc.

Automated Medical Products Corp.

Autonomic Technologies

Avanti Systems, Inc.

Avid Medical, Inc.

Avinger, Inc.

Awareness Technology Inc.

Axiom Medical, Inc.

Axis Dental Corporation

Axo Gen, Inc.

B Braun Medical, Inc.
B Braun Interventional Systems
Burron Mfg. Division

B G Industries, Inc.

Bacchus Vascular

Bacharach, Inc.

Bacterin International, Inc.

Banta Healthcare

Bard Peripheral Vascular

Barnstead International

Baron Medical Corp.

Barriermed, Inc.
Barriermed Glove Co.

Barrx Medical, Inc.

Bausch & Lomb, Inc.

Baxa Corporation

Baxter Healthcare Corp.
Baxter Compass

Bayer Corporation
AGFA Division

Bayer Healthcare
Diagnostics

Beacon Endoscopic

Beckman Coulter, Inc.
Australia
Kentucky
Primary Care Diagnostics

Becton, Dickinson & Company
Acutecare
Becton Dickinson Division
Diagnostic Instrument Systems
Immunocytometry Systems
Infusion Systems
Labware
Medical Glove Division
Medical Technique Products
Microbiology Systems
Phase Medical, Inc.
Pharmaceutical Systems
Vacutainer Systems
Vascular Access

Beiersdorf, Inc.
Beiersdorf Medical
Jobst Institute, Inc.

Bel-Art Products
Maddak, Inc.

Belle de St. Claire

Belport Company
Gingi-Pak

Bemis Health Care, Inc.
Bemis Mfg. Co.

Bergan Mercy, Inc.

Berkley Medical Resources, Inc.

Biddle & Crowther Company

Bio Compression Systems

Bio Derm, Inc.

Bio Medical Enterprises, Inc.

Bio Merieux, Inc.

Bio Plas, Inc.

Bioaccess, Inc.

Biocompatibles, Inc.

Biocompatibles International PLC
Biocompatibles Cardiovascular, Inc.

Biological & Environmental Control Labs

Biomed Diagnostics, Inc.

Biomed Packaging Systems, Inc.

Bio-Medical Devices, Inc.

Biomerieux, Inc.

Biomerix Corporation

Bioplate, Inc.

Biopro

Bio-Rad Laboratories, Inc.
Bio-Rad Lab Inc Clinical Diag. Group
Redmond Operations

Biosculpture Technology, Inc.

Bioseal Medical Packaging Concepts

Biosearch Medical Products, Inc.

Biosphere Medical, Inc.

Biotek Instruments, Inc.

Biotrol International
Pro-Dex, Inc.

Bioventus LLC

Birchwood Laboratories, Inc.

Blackstone Medical, Inc.

Block Medical, Inc.

Blue Endo

Boehringer Laboratories, Inc.

Boekel Industries, Inc.

Boots-Celltech Diagnostics Ltd.

Boston Endo-Surgical Technologies, Inc.

Boston Scientific Corporation
Advanced Bionics
Cardiac Assist
EPT
Interventional Technologies, Inc.
Meadox Medicals, Inc.
Medi-Tech
Microvasive Endoscopy
Microvasive Urology
Scimed
Target Therapeutics

Bound Tree Medical

Brennen Medical, Inc.

Breveon, Inc.

Bridger Biomed, Inc.

Briggs Medical Service Corp.

Brinkmann Instruments Co., Inc.

BSD Medical Corporation

Bulbtronics Inc.

Registered Labelers

Burton Medical

Busse Hospital Disposables

C R Bard, Inc.
- Bard Access Systems
- Bard Canada, Inc.
- Bard Cardiopulmonary
- Bard Critical Care Div.
- Bard Electrophysiology
- Bard Interventional Products
- Bard Medical
- Bard Medsystems Division
- Bard Radiology Division
- Bard Reproductive Systems
- Bard Urological Division
- Bard Vascular Systems Division
- Birtcher Medical
- Davol Inc/Bard Access
- Medchem Products, Inc.
- USCI Division

Cabot Medical Corp.

Cactus LLC

Calhoun Vision, Inc.

Cambridge Heart, Inc.

Candelis, Inc.

Carbon Medical Technologies

Cardiac Science Corporation

CardiacAssist, Inc.

Cardica, Inc.

Cardinal Health
- Alaris Medical Systems

Cardinal Scale Mfg. Co.
- Detecto Scale

Cardiogenesis Corp.

Cardiomems, Inc.

Cardiovascular Dynamics, Inc.
- Interpoint Medical Systems

Cardiovascular Innovations, LLC

Careside Medical

Carestream Health, Inc.

Carl Parker Associates, Inc.
- Dental Materials Group
- Mydent Corporation

Castle Professional Services, Inc.
- Cardio Medical Solutions, Inc.

Catheter Connections, Inc.

Cayenne Medical, Inc.

Cederroth, Inc.

Celera Corporation

Celerus Diagnostics

Cellay, LLC

Cellera, LLC

Centrix, Inc.

Century Plastics
- Mac-Lee Medical Products

Cerapedics, Inc.

Cetylite Industries, Inc.

Chatsworth Latex, Inc.

Chesebrough-Ponds, Inc.
- Home Services Division

Chester Labs, Inc.

Chestnut Medical

Children's Hospital Medical Center

Christie Medical Holdings, Inc.

Churchill Medical System, Inc.

Cianna Medical Inc.

Cida

Cincinnati Surgical Company

CIRCA Scientific, LLC

Circon Corporation
- Cabot Medical Corporation

Citra Anticoagulants, Inc.

Civco Medical Solutions

Clearmedical

Clinical Innovations, Inc.

Clinical Instruments International, Inc.

Clinimed, Inc.

Clinipad Corp.

CMP Industries LLC

Coalescent Surgical, Inc.

Coaxia, Inc.

Codonics, Inc.

Coeur, Inc.
- Coeur Medical

Coherex Medical

Collagen Matrix, Inc.

Coloplast, Inc.
- Coloplast AS

Coltene/Whaledent, Inc.

Columbia Diagnostics, Inc.

Comfortex, Inc.
- Avatar Enterprises

Compression Therapy Concepts

Computer Sports Medicine, Inc.

Con Med

Conceptus, Inc.

Conforma Laboratories, Inc.

Conformis, Inc.

Conmed Corp.
- Andover Medical
- Aspen Laboratories, Inc.
- Linvatec

Conor Medsystems

Consolidated Polymer Tech., Inc.

Contec, Inc.

Control Company

Control Medical Technology

Cook Group, Inc.
- Cook Biotech, Inc.
- Cook Urological
- Wilson-Cook Medical, Inc.

Cooley & Cooley, Ltd.

Cooper Biomedical, Inc.

Coors Ceramics Company

Corning, Inc.

Correx, Inc.

Cottrell, Ltd.
- Advance Suture, Inc.
- Alliance Western Mfg.
- Prochem Company

CP Medical, Inc.
- Theragenics

CPAC
- Allied Diagnostic Imaging Resources

Cretex
- RMS Company

Critical Diagnostics

Critacare, Inc.
- Infusion Devices

Crosstex International

Crosstrees Medical, Inc.

Cryovascular Systems, Inc.

CSC Scientific Co., Inc.

Cura Medica LLC

Cure Medical LLC

Curexo Technology Corporation

Currie Medical Specialties

Curtin Matheson Scientific, Inc.

Cuyahoga Falls General Hospital

Cygnus, Inc.

Cypress Medical Products, LP

Cytogen Corporation

CytoSorbents, Inc.

Dade International
- Dade Chemistry Systems, Inc.

Dale Medical Products, Inc.

Data Medical

Datascope Corporation

DCI International

Decon Laboratories

Delcath Systems, Inc.

Delta Gloves

Deltec
- Graseby Medical, Inc.

DeNovo Products, LLC

Registered Labelers

Dental Technologies, Inc.

Den-Tal-Ez, Inc.
- Custom Vacuum
- Den-Tal-Ez Equipment
- Star Dental

Denticator International, Inc.

Dentsply International, Inc.
- Ash USA
- Ceramco, Inc.
- Dentsply Caulk De Mexico SA
- Dentsply Endodontics
- Dentsply GmbH
- Dentsply Industria E Comeri
- Dentsply, Ltd.
- Preventive Care Division LP
- Prosthetics Division
- Ransom & Randolph Co.
- The L D Caulk Co.

DePuy, Inc.

DePuy Ace Medical

Deroyal Industries, Inc.

Deroyal Technologies, Inc.

Devax, Inc.

Devicor Medical Products, Inc.

Dexide, Inc.
- Iotec Industries
- Nurse Assist
- Trotec Medical Corporation

Dey Laboratories LP

DGIMED Ortho, Inc.

DHD Healthcare

Diamatrix, Ltd.
- Int'l. Science & Technology, LP

Diasorin, Inc.
- Diasorin SPA

Difco Laboratories, Inc.

Dipro Diagnostic Products

Disc Motion Technologies

Dittmar, Inc.

Dixtal Medical, Inc.
- Dixtal Biomedica Indus. e Comercio, Ltd.

DJ Orthopedics, LLC

DOC Development, Inc.

Doctor Down, Inc.

Doctors Regional Medical System

Doctors Research Group, Inc.

Dow Corning Corp.

Drummond Scientific Company

Duchesnay USA, Inc.

Duplex Products, Inc.

Dux Dental

Dynarex Corporation

Dynatech Laboratories, Inc.

E I Dupont de Nemours
- Dupont Critical Care-Med Prod. Dept.
- Medical Products Department

Eastern Systems Research, Inc.
- ESR Medical Products Group

Eastman Kodak Company

Eclipse Medical, Inc.

Eco Lab

EFOS, Inc.

Ekos Corporation

EKR Therapeutics, Inc.

Electromed, Inc.

Electromedics, Inc.

Eli Lilly & Company
- Dista Products

Embla Systems

EMD Chemicals, Inc.

Emergency Medical Education Tech Sys.

Encore Medical LP
- Encore Soft Goods

Endius, Inc.

Endocardial Solutions, Inc.

EndOclear, LLC

Endodent, Inc.

Endologix, Inc.

Endoscopic Technologies, Inc. dba Estech

Engineered Medical Systems

Enhancement Medical, LLC

Enochs Manufacturing, Inc.

Enpath Medical, Inc.
- Lead Technologies Div.

ENT Innovations
- Cytophil, Inc.

Entellus Medical

Enterprise Systems, Inc.

Enzyme Industries, Inc.

Epimed International, Inc.

Erie Scientific International
- Barnstead International

Essential Dental Systems, Inc.

Ethicon Inc. and Ethicon Endo

Ethox Corporation

ev3 Inc.

Evergreen Scientific, Inc.

Exactech Inc.

Exami-Gowns, Inc.

Extremity Medical LLC

Eyekon Medical, Inc.

E-Z-EM, Inc.

Fenem, Inc.

Fenwal, Inc.

FFM Med Reps, LLC
- Excel Medical Products, LLC

Fiberoptic Components, LLC

Fine Surgical Instruments, Inc.

Fisher Healthcare/Curtin Matheson Scient.
- Pacific Hemostasis

Fisher Scientific
- Chemical Mfg. Division
- Diagnostics Division
- Instrument Mfg. Division

Fixes 4 Kids, Inc.

Florida Medical Industries, Inc.

Flow X-Ray Corp.
- Wolf X-Ray Corp.

Flowmedica, Inc.

Foremost Dental Manufacturing Co., Inc.

Foxhollow Technologies, Inc.

Fresenius Pharma
- Fresenius AG

Fujifilm
- Fujifilm Electronic Materials USA, Inc.

Fujisawa USA, Inc.

Fusion Medical Technologies, Inc.

Galileo Corporation
- Leisegang Medical, Inc.

Galt Medical Corp.
- Theragenics

Gambro Co.

Gamma Biologicals, Inc.
- Division of Imucore

Gateway Medical, Inc.

Gaymar Industries, Inc.
- Medisearch PR, Inc.

Gaymar Industries, Inc.

GC Corporation
- GC America, Inc.

GE Healthcare

Geisinger Foundation
- Geisinger System Services

Gelman Sciences, Inc.

Gendex Corporation
- Gendex Dental X-Ray
- Gendex Europe
- Midwest Dental Products
- Universal X-Ray

General Glassblowing Co., Inc.

Generic Medical Devices

Genetic Laboratories Wound Care, Inc.
- Derma Services

Genetics Systems Corp.

Registered Labelers

Genii, Inc.
Genzyme Corporation
George Medical, LLC
G-F Health Products, Inc.
GFC Bridgeview, Inc.
  Derma Care Div.
Ghost Mfg. LLC
GI Dynamics Inc.
Gibbons Surgical Corporation
Gillette
  Oral-B Laboratories
Gimbel Glove Company, LLC
  Gimbel Medical Glove Company, LLC
Global Manufacturing Industries, LLC
Global Medical Products, Inc.
  dba Tava Surgical Instruments
Globe Enterprises, Inc.
Good Samaritan Hospital
  Legacy Health System
Goosen Enterprises, Inc.
GRA Medica
Graham-Field
  Everest and Jennings
Grande Ronde Hospital
Graphic Controls Corporation
Greenville Hospital System
Grieshaber Mfg. Co., Inc.
GTI Diagnostics
Guidant Corporation
  Cardiac Rhythm Management
  Guidant CVS
  Vascular Intervention
Guided Therapeutics Inc.
GWR Medical, Inc.
Gynecare, Inc.
Gyrus Ent
Gyrus Medical
Gyrx, LLC
  Endox LLC
H W Andersen Products, Inc.
Hager & Werken
  Hager Worldwide
Hamamatsu Corp.
  Photonics Management Corp.
Hantel Technologies, Inc.
Harbor Medical Devices, Inc.
Hard Mfg. Co.
Hardwood Products Co.
Harry J. Bosworth Co.
Harvest Technologies
Havel's, Inc.
Hawaii Medical, LLC
Hayes Handpiece Co.
Health Care Logistics, Inc.
Health Services Corp. of America
Healthcare Materials Network
Healthcare Products Plus
Healthlink, Inc.
Healthmark Industries Co.
Health-Mor Industries, Inc.
  Health-Mor Personal Care Corp.
Heart Technology, Inc.
Heart Ware, Inc.
Hearten Medical, Inc.
Heartport
Hedwin Corp.
Helena Laboratories, Inc.
Henry Schein, Inc.
Henry Troemner, Inc.
Heraeus Kulzer, Inc.
  Dental Products Group
Heuer Time & Electronics Corp.
Hill-Rom, Inc.
  Medic PRN
Hobbs Medical, Inc.
Hospira, Inc.
Hospital Mktg. Services Co., Inc.
Hotspur Technologies, Inc.
Howard Medical Company
Howard Young Medical Center
Hudson Respiratory Care, Inc.
Hu-Friedy Mfg. Company
  Hu-Friedy Mader Medical
Huntleigh Technology, Inc.
  Huntleigh Healthcare, Inc.
Huot Instruments, LLC
HWI
Hycor Biomedical Inc
Hydrocision Inc
Hydrotech Enterprises
Hy-Tape International
Iconacy Orthopedic Implants, LLC
ICP Medical
ICU Medical, Inc.
Ideal Implant Incorporated
IDEV Technologies, Inc.
IlluminOss Medical Inc.
Imagyn Medical Tech
Imperial Medical Technologies, Inc.
Implant Innovations, Inc.
Incisive Surgical, Inc.
Independent Medical Co-op (IMCO)
Ind. for the Blind and Visually Impaired
Infraredx, Inc.
Infusive Technologies, LLC
Inneroptic Technology, Inc.
Innerspace Corp.
Innovasive Devices, Inc.
Innovative Healthcare Corporation
Innovative Neurotronics, Inc.
  Hanger Orthopedic Group, Inc.
Innovative Therapies, Inc.
Inova Diagnostics, Inc.
Inova Labs
Inovise Medical, Inc.
INRAD, Inc.
Integra Lifesciences Corporation
  Integra Luxtec, Inc.
  Integra Life Sciences
  Integra Pain Management
  Integra Radionics
Integrity Life Sciences, LLC
Interflo Medical
International Biophysics Corp.
International Business Solutions Alliance
International Equipment Company
International Medical Research & Design
International Win, Ltd.
Interpore Cross International
Interpore Orthopaedics, Inc.
Intersect ENT
Intersect Partners LLC
Intraluminal Therapeutics
Intra-Sonix, Inc.
Intrinsic Therapeutics, Inc.
Intuitive Surgical, Inc.
Invitro Systems, Inc.
Invotec International, Inc.
Invuity, Inc.
Irrimax Corporation
Irvine Biomedical, Inc.
IsoAid, LLC
Isolyser Company, Inc.
Isotis Orthobiologics
Ivera Medical
Ivoclar Vivadent, Inc.
Ivy Sports Medicine, LLC
J & R Enterprises, Inc.

Registered Labelers

Jaece Industries, Inc.

James River, Inc.
- Health Care Division

James W Daly, Inc.

Japan Medical Dynamic Marketing, Inc.
- Ortho Development Corp.

Jason Marketing Company

JBC Corp.

Jedmed Instrument Company

Jensen Tools, Inc.

Johnson & Johnson
- Advanced Sterilization Products
- Codman & Shurtleff, Inc.
- Cordis Biot Div.
- Cordis Miami Div.
- Cordis Roden Div.
- DePuy Acromed
- DePuy Mitek
- Independence Technology
- J&J Dental Care
- J&J Hospital Services
- J&J Consumer Products Co.
- J&J Medical, Inc.
- J&J Medical (China) Ltd
- J&J Professional, Inc.
- Janssen Pharmaceutical, Inc.
- Lifescan, Inc.
- McNeil Pharmaceutical Canada
- OMJ Pharmaceuticals, Inc.
- Ortho Clinical Diagnostics
- Ortho-McNeil Pharma. Corp.
- Sarl
- Therakos

Jordco, Inc.

Justrite Manufacturing Company

K2M, Inc.

Kareco International, Inc.

Katena Products, Inc.

KC Biomedix

K-C Medical, Inc.

KCI New Technologies, Inc.
- Kinetic Concepts, Inc.

Keller Medical Specialties, Inc.

Kenad SG Medical, Inc.

Kendro Laboratory Products

Kennedy Memorial Hospitals

Kensey Nash Corporation
- (dba - DSM BioMedical)

Kerberos Proximal Solutions, Inc.

Kerr Corporation
- Alden

Keystone Industries
- Mizzy, Inc.

Keystone Manufacturing

Kimberly Clark Corp.
- Health Care Products Group

Kinamed, Inc.

Kinetic Concepts, Inc.

King Pharmaceuticals, Inc.

Kips Bay Medical, Inc.

Kirschner Medical Corp.

Kleen Test Products

KMedic

Knoll Pharmaceutical Co.

Koehler Instrument Co., Inc.

Kyphon, Inc.

L&R Mfg. Company

Lab Depot, LLC

Labconco Corporation

Lab-Line Instruments, Inc.

Laborie Medical Technologies

Lafayette Pharma., Inc.

Lake Hospital Systems, Inc.

Lake Region Mfg., Inc.

Lakeside Mfg., Inc.

Lamico, Inc.

Lang Dental Mfg. Co., Inc.

Lares Research

Latexx Partners Berhad
- Medtexx Partners, Inc.

Lee Memorial Hospital

Leeder Group, Inc.

Leica
- Optical Products Division

Leomed, LLC

LGM International, Inc.

Lifecell Corporation

Life Instrument Corp.

Lifestream International, Inc.

Life-Tech, Inc.

Light Age, Inc.

Lighthouse for the Blind

Linvatec
- Hall Surgical

Little Rapids Corporation

Lohmann GmbH & Co.
- Carapace, Inc.

Loma Vista Medical

Lone Star Medical Products, Inc.

Lone Star Technologies

Lorrex Health Products

Louisville Pharmacy

Lumend, Inc.

Lumiquick Diagnostics, Inc.

Lumitex Medical Devices, Inc.
- Surgical Division

Maersk Medical, Inc.

Magellan Biosciences
- Dynex Technologies
- ESA Biosciences
- TREK Diagnostics Systems

Magnatone Hearing Aid Corp.

Mako Surgical Corp.

Mallinckrodt Baker, Inc.
- Mallinckrodt Chemical
- Mallinckrodt Anesthesia Products
- Mallinckrodt Anesthesiology
- Mallinckrodt Diag. Products Div.
- Mallinckrodt Medical, Inc.

Mann Chemical Corp.

Maramed Orthopedic Systems

Mark Clark

Maryland Plastics, Inc.

Masimo Corporation

Mason Tayler Med. Products Corp.

Matrx Medical, Inc.

Matrix Surgical Holdings, LLC

Max Mobility, LLC

Maxxim Medical
- Containment Products
- Medical Diagnostics
- Medical Nonwovens & Gloves
- Sterile Trays/ Non-sterile Kit

MCM Environmental Technologies Ltd
- GMS Marketing

MD Industries, Inc.

Medcanica, Inc.

Medegen, Inc.

Medegen Medical Products

Medela Healthcare

Medennium, Inc.
- Eyepx LLC

Medex, Inc.
- Medex Medical Mktg.

Med-Fit Systems, Inc.

Medgyn Products, Inc.

Medica Holdings, LLC

Medical Action Industries, Inc.

Medical Chemical Corporation

Medical Concepts Dev., Inc.

Medical Designs LLC

Medical Device Technologies, Inc.
- Angiotech Pharmaceuticals, Inc.

Medical Devices International
- MDI Plasco, Inc.

Registered Labelers

Medical Facets NC, LLC
Medical Illumination Int'l., Inc.
Medical Infusion Technology
Medical Instrument Dev. Labs, Inc.
Medical Inventors Corporation. Inc.
Medical Laboratory Automation, Inc.
Medical Latex Corp.
Medical Products Laboratories, Inc.
Medical Resources Int'l.
  BNT Co., Inc.
Medication Delivery Devices
Medichoice (Owens & Minor)
Mediflex, Division of Flexbar Machine Corp.
Medigroup Inc. / Janin Group
Meditech International Corp.
Medivance, Inc.
Medivest, Inc.
Medline Industries, Inc.
Medlogic
Medovations, Inc.
Medrad, Inc.
MedShape, Inc.
Medtek Devices, Inc.
  Buffalo Filter
Medtrex Incorporated
Medtronic, Inc.
  Biotek International SPA
  Blood Systems
  Cardiopulmonary
  Cardiorhythm
  CAS Venture
  DLP
  Drug Administration Systems
  Interstim Venture
  Interventional Vascular Inc
  Medtronic Bio Medicus
  Medtronic, Inc (CPRA)
  Merocel Scientific Division
  Neurological Division
  Pacing Business Unit
  Physio-Control Corp.
  Vascular Division
  Vitatron, Inc.
  Xomed
Mentor Corp.
Mercator MedSystems, Inc.
Merck-Medco Managed Care, Inc.
  SysteMed
Mercy Healthcare System
Merge Healthcare
Meridian Medical Systems
Merit Medical Systems
Merz Aesthetics, Inc.
Mesa Laboratories, Inc.
Methodist Hospital of Indiana, Inc.
Methodist Hospitals of Memphis
Metrex Research Corporation
Metric Medical Devices, Inc.
Mettler Toledo
Micro Motors, Inc.
Microaire Surgical Instruments
Micromed Technology, Inc.
Micromedical Technologies, Inc.
Micromedics
MicroPhage, Inc.
MicroPort Orthopedics, Inc.
Micro-Scientific Industries, Inc.
Microtherapeutics, Inc.
Microvention, Inc.
Microvision, Inc.
Micrus Corporation
Midwest Textiles, Inc.
Millennium Biomedical, Inc.
Miltex, Inc.
Milton Roy Company
  Analytical Product Division
Mimedx Group, Inc.
Mindframe, Inc.
Mindways Software, Inc.
Minnow Medical, Inc.
Minrad, Inc.
Mirecal, LLC
  Remicalm, LLC
Misonix, Inc.
Mizuho OSI, Inc.
MM Herman & Associates, LLC
  Flu Armour
  Herman Products
MMS, LLC
Mobius Therapeutics, LLC
Modec, Inc.
Molded Products
Molecular Biometrics, Inc.
Momelan Technologies, Inc.
Moore Business Forms, Inc.
Mortan, Inc.
Mortara Instrument, Inc.
Motloid/Yates & Bird
  Bird-X, Inc.
Moximed, Inc.
M-Pact Worldwide, LLC
MPL Technologies
MPS Acacia
MRLB International, Inc.
Musculoskeletal Transplant Foundation
Myco Medical
Myelotec, Inc.
Nanogen, Inc.
Nanoscale Materials, Inc.
Nanosphere, Inc.
Nasiff Associates, Inc.
National Distribution and Contracting
National Standard Company
  Medical Products Division
Natus Medical, Inc.
Nellix, Inc.
Neocare
Neodevices, Inc.
Neotract, Inc.
Neptune Products, Inc.
Neucoll
Neuhaus Laboratories, Inc.
NeurOptics, Inc.
Neurorecovery, Inc.
Neurovasx, Inc.
Nevro
New Wave Surgical Corp.
Newby/Coombs, LLC
Newell Rubbermaid, Inc.
  Rubbermaid Commercial Products, LLC
Newtex Industries, Inc.
Nexcore Technology
Nextremity Solutions, LLC
Nexus Medical, LLC
Niche Medical
Ni-Med, Inc.
Nmt Medical, Inc.
Nordent Manufacturing Inc.
Norma Tec, Inc.
North Coast Medi-Tek ,Inc.
Northeast Monitoring, Inc.
Northeast Scientific, Inc.
Norvell, LLC
  Body Invest, LLC
Novomedics, LLC
Novoste Corporation
Numed, Inc.
Numia Medical Technology, LLC
Nutek Orthopaedics, Inc.
Nxstage Medical, Inc.

Registered Labelers

Oasis Medical
OBP Corporation
Oculus Surgical, Inc.
Ohaus Scale Corporation
Olson Medical Sales, Inc.
Olympus Biotech Corporation
Omega Medical Products Corp.
Omega Surgical Instruments, Inc.
Omni International, LLC
Omni-Flow, Inc.
Omnisonics Medical Technologies
Omni-Tract Surgical
  Integra Life Sciences
One Cell Systems, Inc.
Ongoing Care Solutions
Ophthalmic Innovations International, Inc.
Optical Radiation Corp.
Opticon Medical
Optimedica Corporation
Opus Medical, Inc.
Ora Innovations, Inc.
Orbus Medical Technologies, Inc.
Origen Biomedical
Ortho Technology
Orthofix Inc.
OrthoPediatrics Corp.
Oscor Inc.
Osprey Medical Inc.
Osseon Therapeautics Inc.
Ostex International, Inc.
Ostial Corporation
Ostial Solutions, LLC
Owens-Illinois, Inc.
  Owens Brigam
  Owens-Illinois Health Care Group
Pacira Pharmaceuticals, Inc.
Packaging Services Corp. of Kentucky
  Olsen Medical
Pall Corp
  Pall Biomedical Products Co.
Palmero Health Care
Parcus Medical, LLC
Parkell, Inc.
Parker Medical Associates
Pascal Company, Inc.
Patterson Dental Company
Patton Surgical Corporation
PDI/Professional Disposables Int'l.
Pearson Dental Supply Co.
Peerless International, Inc.
Pelikan Technologies, Inc.
Pennsylvania Engineering Company
Penumbra, Inc.
Percutaneous Systems, Inc.
Perfecseal
  Medi-Plus
Perigon Medical Distribution Group
Peripheral Visions, Inc.
Pfizer Hospital Products Group, Inc.
  American Medical Systems, Inc.
  Schneider (USA)
  Shiley, Inc.
  Valleylab, Inc.
Pfizer Warner Lambert Co.
  Parke-Davis Division
Pharmacia, Inc.
Pharmacia Ophthalmics
Pharma-Plast, Inc.
  Pharma-Plast Denmark
  Pharma-Plast USA
Phase One Medical
Philips Medical Systems
Pilling Weck
  Weck Closure Systems
Pinnacle Products, Inc.
Pioneer Surgical Technology
Plastek Industries, Inc.
Plasti-Products, Inc.
Pluromed, Inc.
Poly Vac
Pope Scientific, Inc.
Porex Technologies Corp. of Georgia
  Porex Surgical, Inc.
Porton Diagnostics, Inc.
  Porton International PLC
Posey Company
Pouch Support Systems, Inc.
Power Medical Interventions, Inc.
Practicewares Dental Supply
Precision Dynamics Corp.
Precision Laboratory Plastics, Inc.
Precision Scientific, Inc.
Precision Systems, Inc.
Precision Vascular Systems
Premier Dental Products Company
Premium Plastics, Inc.
Presby Corporation
Preventive Technologies
Principle Business Enterprises
Professional Hospital Supply, Inc.
Professional Medical Products
Professional Products, Inc.
  Government Sales Division
Prograft Medical, Inc.
Progressive Dynamics, Inc.
Proma, Inc.
Promex Technologies, LLC
Propper Manufacturing Co., Inc.
Protekmed, LLC
Providence Medical Technology, Inc.
PSC of Kentucky
  Olsen Medical
PSS World Medical
  Gulf South Medical Supply
PT Eka Wira Asia
Puerto Rico Hospital Supply, Inc.
Pulmonetic Systems, Inc.
  Viasys Healthcare, Inc.
Pulmonx, Inc.
Pulpdent Corporation
Puritan-Bennett Corporation
  Bennett Group
  Boston Division
  Cyrogenic Equipment Division
  Ireland, Ltd.
  Medicomp, Inc.
  Oxygen Concentrator Division
  Portable Ventilator Division
  Puritan Group
Pymah Corp.
  ATI Division
QBC Diagnostics
Qorpak
QRS Diagnostic, LLC
Quantimetrix Corporation
Quintus, Inc.
R4 Vascular, Inc.
Radius Medical Technologies, Inc.
Radtech, Inc.
RAMM Technologies LLC
Ranfac Corporation
RD Medical Manufacturing, Inc.
Reckitt & Colman, Inc.
  R & C Probrands
Red Bird Service
  Ricca Chemical Company, LLC
Regent Hospital Products, Ltd.
  London International Group PLC
Remicalm, LLC
Reshape Medical, Inc.
Respironics, Inc.

Registered Labelers

Restore Medical, Inc.
Rex Medical LP
Rhythmlink International, LLC
Ricca Chemical Company, LLC
Richard-Allan Medical Industries
  Image & Medical Technologies
Rinn Corp.
Riverside Community Hospital
Roche Diagnostic Systems
Rox Medical, Inc.
Roxane Laboratories, Inc.
Royce Medical
Rumex International Co.
Sadra Medical Corporation
Safco Dental Supply Co.
Safety Medical International, Inc.
Saf-T-Med
Sage Products, Inc.
Saint Gobian Performance Plastics
Sakura Finetek USA, Inc.
Samco Scientific, Inc.
Sanovas, Inc.
Savannah River Mills, Inc.
SBW Medical Products, Inc.
Scandius Biomedical, Inc.
Schleicher & Schuell, Inc.
Schwarz Pharma
  Kremers Urban Co
Science, Inc.
Scientia LLC
Scientific Equipment Products Co.
Scientific Safety Solvents
Scieran Technologies, Inc.
Scigen Scientific
Scion Cardio-Vascular, Inc.
Scitech Dental, Inc.
Scivolutions, Inc.
Sea Spine, Inc.
Seamless Hospital Products Co.
Second Sight Medical Products, Inc.
Semler Technologies, Inc.
Sempermed USA, Inc.
Senorx, Inc.
Sentreheart, Inc.
Septodont, Inc.
Seradyn, Inc.
  Fisher Scientific International
Serim Research Corporation
Shamrock Scientific Specialty Systems
Sharklids Eye Gear
Sharn Anesthesia
Sharon Metal Stamping Corp.
  Walk on Air
Sheldon Manufacturing, Inc.
Sherwood Pharmaceutical Co.
Si Bone, Inc.
Sicor, Inc.
  Gensia Pharmaceuticals, Inc.
Sigma Rx LP
Silicon Valley Medical Instruments, Inc.
Simpact, LLC
SinuSys Corporation
Skedco, Inc.
Sklar Corporation
Smart Medical Technology, Inc.
Smartpractice
  Smartcare
Smartpill Corporation
Smith & Nephew
  Endoscopy Division
  Orthopaedic Division
  Orthopaedics AG (Switzerland)
  Orthopaedics Co., Ltd (Beijing)
  Orthopaedics GmbH (Germany)
  Orthopaedics, Ltd.
  United Wound Management Division
Somatics, LLC
Somnetics International
Somnus Medical Technologies
Sonic Innovations, Inc.
Sonotech, Inc.
Sony Corporation
Sorb Technology, Inc.
Sorin Biomedica
  Cobe Cardiovascular UK
Sota Medical Products
Sorin Group,USA, Inc.
Sourceone Healthcare Technologies
Spacelabs Medical, Inc.
Span-America Medical Systems, Inc.
Sparta Surgical Corporation
  Sparta Maxillofacial Products, Inc.
Specialized Health Products
Specialty Surgical Instrumentation, Inc.
Spectra Medical Devices, Inc.
Spectramed, Inc.
Spectranetics Corporation
Spectrum Designs Medical
Spectrum Medical Industries, Inc.
Spinal Kinetics
SpinalMotion, Inc.
Spinal Simplicity, LLC
SpineCraft
Spire Corporation
  Spire Biomedical
SRI/Surgical Express, Inc.
Sroufe Healthcare Products
  Remington Products
SRS Medical Systems, Inc.
SS White Burs, Inc.
St. Francis Regional Medical Center
St. Francis-St. George Hospital
St. Gobain Performance Plastic
St. Johns Mercy Medical Center
St. Jude Medical
  Diagnostic Division, Inc.
St. Jude Medical CRMD
St. Peter Hospital
St. Vincent Hosp. & Hlth. Care Ctr.
Staco Energy Products Company
Standard Register
  Advanced Medical Systems
Starchem, Inc.
Starion Instruments
Starline Dealers Association
Statcorp, Inc.
Step Forward Co.
Stereotaxis, Inc.
Steris Corporation
  Amsco Canada - Ingram & Bell
  Amsco Service Co. - Ingram & Bell
Stern Metals, Inc.
  Sterngold
Storz-GmbH
  American Cyanamid
Streck Laboratories, Inc.
Structure Probe, Inc.
  SPI Supplies Division
Stryker Corporation
  Dimso Division
  Stryker Ascent
  Stryker Endoscopy Division
  Stryker Dental
  Stryker Global Quality & Operations
  Stryker Howmedica Osteonics
  Stryker Instruments
  Stryker Medical
  Stryker Orthopaedics (Otis Med)
  Stryker Osteo AG
Sultan Chemists, Inc.
  Sultan Medical
Sultan Dental Products, Ltd.

Registered Labelers

Sulzer Carbomedics

Sulzer Medica
  Sulzer Intermedics USA

Summit Medical Center

Sun Scientific, Inc.

Sun-Med

Sunoptic Technologies

Superdimension, Inc.

Superior Health Care Group, Inc.

Surgical Specialties Corporation

Surgical Warehouse, Inc.

Surgicot, Inc.
  Value Medical Products, Inc.

Surgimedics, Inc.
  Denver Biomedical, Inc.

Surx, Inc.

Sutura Inc.

Svelte Medical Systems

Sybron Chemicals
  Clinical Technology Div.

Sybron Corp.
  Analytical Products Div.
  Barnstead Co.
  Mediatech Div.
  Panorama Plastics
  Sybron Endo
  Thermolyne Corp.

Sybron Corpnalge Nunc Int'l.
  Apogent

Sybron Dental Specialties
  Ormco

Symmetry Medical USA, Inc.

Synergetics USA, Inc.

Synergy Biomedical, LLC

Synthemed, Inc.

Syntheon, LLC
  ID LLC

Synthes

Synthes Spine Company LP

Synthes USA
  Maxillofacial Division

T.C. Dental Products, Inc.

Tandem Medical, Inc.

Taut, Inc.

Taylor Bio-Medical, Inc.

Tecator, Inc.

Techdevice Corporation

Tekia, Inc.

Teledyne Technologies, Inc.

Teledyne Water Pik

Teleflex CT Devices, Inc.

Tempur-Pedic North America, LLC

Tenet Health

Terumo Medical Corp.
  Terumo Europe N.V.

Tessek

Thayer Intellectual Property, Inc.

The Anspach Effort, Inc.

The Burrows Company

The Cheshire Medical Center

The Coopers Companies, Inc.
  Cooper Surgical, Inc.

The Gerresheimer Group
  Kimble Glass
  Kontes Glass, Inc.

The GID Group, Inc.

The Hygenic Corp.

The Morel Company

The Procter & Gamble Company
  Norwich Eaton Pharmaceuticals

The Texwipe Company

The Torrent Corp.

The Upjohn Company
  Upjohn Pharmaceuticals

Thermo Cardiosystems, Inc.

Thermo Fisher Scientific

Thermopeutix, Inc.

Thomas Jefferson University

Thomas Scientific

Thompson Surg. Instruments, Inc.

Tian Medical LLC

TIDI Products

Timemed Labeling Systems

Tissue Link Medical, Inc.

Titan Spine, LLC

TMJ Medical

Top Spins, Inc.

Topcon Medical Laser Systems, Inc.

Transamerica Delaval Med. Prod.

Transdermal Cap Inc.

TransEnterix

Transgenomic, Inc.

Transvascular Inc.

Tredegar, Inc.
  Therics, Inc.

Tri State Distribution, Inc.

Tri-Anim
  eValueMed
  Magnus

Tri-Anim Surgical Solutions

Tri-Ject International Corp.

Trimed, Inc.

Trimedyne, Inc.

Trimira LLC
  Remicalm LLC

Trinity Medical Implants, Inc.

Trinity Sterile, Inc.

Trireme Medical, Inc.

Tri-Star Medical

Trudell Marketing International
  Northgate Technologies, Inc.

Turenne Pharmed Co.
  Turenne & Associates LLC

Tyco Healthcare
  Tyco Healthcare Ludlow

UARCO, Inc.

UCLA Medical Center

Ultradent Products, Inc.

Uniforms Manufacturing, Inc.

Unimed Surgical Products, Inc.

Unique Technologies, Inc.

United States Surgical Corp.
  HTR Sciences
  Surgical Dynamics
  Tyco Healthcare

University of California Med. Ctr.

University of Michigan Hospitals

Uresil, LP

Urologix, Inc.

US Endoscopy, Inc.

US Medical Instruments, Inc.

US Spinal Technologies, LLC

Utah Medical Products, Inc.

Vacalon Company, Inc.

Vadus, Inc.

Vapotherm, Inc.

Vascular Designs, Inc.

Vascular Solutions

Vascular Technology

Vastek

Vastrac, LLC

Vector, Inc.

Velocity Medical Solutions

Venetec International

Ventrex, Inc.

Veratex

Veritas Medical Innovations

Vertex Industries, Inc.
  Torbal Division

Vertis Neuroscience

Registered Labelers

Vesocclude Medical, LLC

Viasys Healthcare, Inc.
- Bird Products
- Corpak Medsystems
- Medical Data Electronics
- Nicolet Biomedical
- Sensormedics Corp.

Vidamed, Inc.

Viking Systems, Inc.

Viral Control Technology, Inc.

Vision Sciences, Inc.

Visionary Medical Supplies, Inc.

Visitec Company

Vistalab Technologies

Vital Signs, Inc.

Voland Corporation

Volcano Therapeutics, Inc.

VQ Company, LLC

VWR International Co.

W A Baum Co., Inc.

W L Gore & Assoc., Inc.

Wallach Surgical Devices, Inc.

Weck Surgical Systems

Welch Allyn
- Tycos Instruments, Inc.

Welch Allyn, Inc.
Welch Allyn Monitoring

Welcon, Inc.

West Pharmaceutical Services

Wexler Surgical

Whatman, Inc.
- Balston, Inc.
- Balston, Ltd.
- PCI Scientic Supply
- Whatman Far East PTE Ltd.
- Whatman Int'l. Ltd.
- Whatman K K
- Whatman Lab Sales
- Whatman Scientific, Ltd.

Wheaton Industries

Whip Mix Corporation

Whitney Products, Inc.
- Ascent Medical Corp.

Wolfe Tory Medical, Inc.

Wright Medical Technology, Inc.

Wyant Healthcare

Wy'east Medical Corp.

Yellow Springs Instrument Co., Inc.

YMed, Inc.

Young Dental Mfg. Company

Zassi Medical Evolutions
- Bowel Management System LLC

Zefon International
- Zefon Medical Products

Zevex International

Zimmer, Inc.
- Zimmer Biologics
- Zimmer Dental
- Zimmer Orthopaedic Implant Div.
- Zimmer Orthopaedic Surgical Products
- Zimmer Spine
- Zimmer Tmt, Inc.

Zirc Dental Products, Inc.

Health Industry Business Communications Council

Registered Dental Industry Labelers: Accredited Auto-ID Labeling Standards

This list includes dental industry companies that have been assigned a Labeler Identification Code (LIC) by HIBCC or one of our international affiliates. There may be additional labelers that have registered with HIBCC in the medical products market that are also using the Health Industry Bar Code (HIBC) Standard for dental products.

Any organization that is interested in using the HIBC uniform labeling system may apply for the assignment of one or more LICs.

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For more information, please contact the HIBCC office at:

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A-Dec, Inc.
AFP Imaging Corporation
  Dent-X Corporation
Air Techniques, Inc.
  All Pro Imaging
  Jelrus International
Alpro Dental Produkte GmbH
American Dental Cooperative
American Dental Supply, Inc.
ASA Dental SPA
Athena Champion
Austenal Dental, Inc.
Axis Dental Corporation
Banta Healthcare
Basiq Dental BV
Beavers Dental
  Sybron Dental Specialties
Belle De St. Claire
Belport Company
  Gingi-Pak
Bio-Dent
Bredent
Carl Parker Associates, Inc.
  Dental Materials Group
  Mydent Corporation
Candulor AG
Coltene/Whaledent, Inc.
Cominox SRL
Cooley & Cooley, Ltd.
Crosstex International
DeguDent Produkte GmbH
Dental Technologies, Inc.
Den-Tal-Ez, Inc.
  Custom Vacuum
  Den-Tal-Ez Equipment
  Star Dental
Dentaurum GmbH & Co. KG
Dent. JP Winkelstroeter KG
Denticator International, Inc.
Dentrade E.K.
Dentsply International
  Ash Instruments
  Ash USA
  Ceramco, Inc.
  Dentsply Caulk de Mexico SA
  Dentsply Endodontics
  Dentsply France SAS
  Dentsply GmbH
  Dentsply Industria e Comeri
  Dentsply, Ltd.
  Detrey Dentsply, Ltd.
  Preventive Care Div. LP
  Prosthetics Division
  Ransom & Randolph Co.
  The L D Caulk Company
Dr. Ihde Dental AG
Durr Dental AG
Dux Dental
E. Hahnenkratt GmbH
Eco Lab
Edenta AG
Efos, Inc.
Elephant Dental BV
Endodent, Inc.
Enzyme Industries, Inc.
Essential Dental Systems, Inc.
Foremost Dental Mfg. Co. Inc.
Favodent Karl Huber GmbH
Friadent GmbH
GC Corporation
  GC America
Gendex Corporation
  Gendex Dental X-Ray
  Gendex Europe
  Midwest Dental Products
GEBDI Dental Products GmbH
Ghost Mfg. LLC
Gillette
  Oral-B Laboratories
Hager & Werken
  Hager Worldwide
Harry J. Bosworth Company
Harvard Dental Int'l. GmbH
Hayes Handpiece Co.
Heraeus Kulzer, Inc.
  Heraeus Kulzer, Inc. Dental Prod. Grp.
Hu-Friedy Manufacturing Co.
Implant Innovations, Inc.
Itena-Clinical
Ivoclar Vivadent, Inc.
Johnson & Johnson
  J&J Dental Care
Jordco, Inc.
Kentzler-Kaschner Dental GmbH
Lang Dental Mfg Co., Inc.
Lares Research
Lone Star Technologies
Lonestar Technologies, LLC
Maillefer Instruments SA
Medical Products Lab., Inc.

Registered Dental Industry Labelers

M&W Dental
Megadenta Dental Produckte GmbH
Merz + Co. GmbH & Co.
  Merz Dental GmbH
Metalor Dental Products, Ltd.
MPL Technologies
MRLB International, Inc.
Nordent Manufacturing, Inc.
Nordiska Dental AB
Omnident
Ora Innovations, Inc.
Orbis Dental
Palmero Health Care
Pascal Company, Inc.
Patterson Dental Company
Pearson Dental Supply Co.
Peerless International, Inc.
Pinnacle Products, Inc.
Plastek Industries, Inc.
Polydentia SA
Practicewares Dental Supply
Premier Dental Products Co.
Preventive Technologies
Prodonta SA
Prodrive Systems, Inc.
Proma, Inc.
Produits Dentaries SA
Prowital Dental Implants GmbH
Pulpdent Corporation
Regen Lab SA
Reitl Feinwerktechnik GmbH
Rinn Corporation
Safco Dental Supply Co.
Scitech Dental, Inc.
Sedat
Septodont, Inc.
Scheu-Dental
Schutz Dental
SDS Swiss Dental Solutions
Simpact LLC
Sirona Dental Systems GmbH
Southern Dental Industries
Spofa Dental SA
SS White Burs, Inc.
Stern Metals, Inc.
  Sterngold
Stick Tech Ltd
Storz Am Mark GmbH
Stryker Dental
Sultan Chemists, Inc.
  Sultan Medical
Sultan Dental Products Ltd.
Sybron Corporation
  Sybron Endo
Sybron Dental Specialties
  ORMCO
  Sybron Implant Sol. GmbH
T.C. Dental Products, Inc.
Technical & General Ltd.
Teledyne Water Pik
  Teledyne, Inc.
The Dental Directory,
  Billericay Dental Supply Co.
The Hygenic Corp.
Ultradent Products, Inc.
Unor AG
Vacalon Company, Inc.
Veratex
Wasserman Dental-Maschinen
W&H Dentalwerk Burmoos, GmbH
Whip Mix Corporation
WhiteSmile GmbH
Yeti Dentalprodukte GmbH
Young Dental Manufacturing Company
Zimmer Dental
Zirc Dental Products, Inc.
ZL-Microdent Attachment

LABELER IDENTIFICATION APPLICATION

Included here:

- **Instructions**
- **Form A** ***LIC Assignment***
- **Form B** ***Labeler Fees***
- **Form C** ***Certification Report***

Any organization interested in adopting and using the HIBCC uniform bar coding system must apply for assignment of a Labeler Identification Code (LIC).

To apply for assignment of an LIC follow the steps outlined in the instructions which follow.

Health Industry Business Communications Council

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Web site: www.hibcc.org

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■ INSTRUCTIONS: FOR COMPLETING FORM A

(To be completed by all applicants)

Purpose of Application LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

1. Contact Information

Enter your organization's name, address and the name, title and telephone number of your organization's official representative to HIBCC. The official representative will represent your organization in all affairs dealing with your code assignment and HIBCC.

Also enter the name, address, title and telephone number of your organization's chief executive officer (CEO). If your organization is a subsidiary or division of a parent organization, you should enter your subsidiary's or division's CEO, not the parent's.

2. Type of Organization

Check all applicable boxes that describe your organization's business. **Manufacturer of goods** category includes pharmaceuticals, medical devices, invitro diagnostic products and general purpose goods produced or packaged for health care institutional use for operation of the facility of patient personal needs. **Manufacturer of services** category includes computer software and applications, financial administration or related institutional management services. **Health care facility** category includes hospitals, clinics, urgent care centers, ambulatory surgery centers, extended care facilities and blood banks, among others.

3. Transfer of Assignments

LIC assignments are non-transferable.

■ INSTRUCTIONS: FOR COMPLETING FORM B

(*To be completed by all applicants)*

Labeler Fees

Health Care Facility: If you checked the HEALTH CARE FACILITY box under the TYPE OF ORGANIZATION section on Form A, your fee is $100. Complete Section A on Form B.

Manufacturer and Distributor/Wholesaler: If you checked the MANUFACTURER or the DISTRIBUTOR/WHOLESALER box under the TYPE OF ORGANIZATION section on Form A, you must certify your most recent fiscal year sales level by completing the CERTIFICATION REPORT.

■ INSTRUCTIONS: FOR COMPLETING FORM C

(*To be completed by all applicants*)

Specify your annual sales and the fiscal year of those sales. Next, check the appropriate sales category which determines your fee for the primary LIC assigned. Sign and date and return with your application.

LIC: Enter the fee for the LIC in Section A, Form B (determined in the CERTIFICATION REPORT). Sign, date and send forms A, B, and C to: **HIBCC, 2525 E. Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016.** Make all checks payable to HIBCC. If paying by credit card, you may fax forms A, B, and C to HIBCC at (602) 381-1093, or send via email to info@HIBCC.org.

■ FORM A:
LIC ASSIGNMENT

PURPOSE OF APPLICATION: LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

PRIMARY ORGANIZATION:

_____
Organization Name

_____
Name of Official Representative | Title | Phone

_____
Number and Street | PO Box

_____
City/State/Zip Code/Country

_____
E-Mail Address

_____
Name of Chief Executive Officer | Title | Phone

_____
Address, if different from above

TYPE OF ORGANIZATION (*check applicable box for primary market*)

	MEDICAL	DENTAL	ANIMAL HEALTH
❒ MANUFACTURER OF GOODS OR SERVICES	_____	_____	_____
❒ DISTRIBUTOR/WHOLESALER	_____	_____	_____
❒ HEALTH CARE FACILITY OR PROVIDER	_____	_____	_____

FOR OFFICE USE ONLY:

_____
Date Received Application | Fee | Date Received Payment

_____
LIC # | Date Assigned | Initials

■ FORM B:

LABELER FEES (*complete appropriate section*)

SECTION A: Labeler Identification Code (LIC) Assignment

❒ Manufacturer or Distributor/Wholesaler (from Certification Report, FORM C): $_____

OR

❒ Health Care Facility or Provider $100.00

Our organization hereby applies for assignment/registration of a Labeler Identification Code from the Health Industry Business Communications Council.

In making such application, we agree to be bound by all rules and regulations of the Council including, but not limited to the Articles of Incorporation, the Bylaws, the Health Industry Bar Code Standard, and any and all other rules and regulations which the Council has now or may hereafter adopt concerning the use of the Health Industry Bar Code Standard and the Labeler Identification Code assigned. The Council will notify us of our assigned Labeler Identification Code upon receipt of our application fee and Council approval of our completed application.

Our organization hereby agrees to indemnify, and hold harmless, the Health Industry Business Communications Council and their officers, directors, employees, agents, successors and assigns from any and all claims, losses, damages, and liabilities whatsoever resulting from the use or misuse of the Health Industry Bar Code Standard and our assigned Labeler Identification Code.

We understand and acknowledge that the Council has taken all reasonable precautions to prevent the assignment of duplicate Labeler Identification. If duplicate codes are assigned, the liability of the Council shall be limited to a refund of the application's Labeler Identification Code fee or the actual damages, if any, whichever is less.

METHOD OF PAYMENT

❒ Please charge $_____ (amount from above) to my credit card account. ❒ Visa ❒ MasterCard ❒ AmEx

_____

CREDIT CARD NUMBER EXPIRATION DATE CSV/CID CODE

_____

CARDHOLDER'S NAME (as it appears on the card) CARDHOLDER'S SIGNATURE

_____

CARDHOLDER'S ADDRESS

_____

CARDHOLDER'S CITY STATE ZIP/POSTAL CODE

❒ A check in the amount of $_____ (amount from above) made payable to HIBCC is enclosed.

_____

Signature of Official Representative Title

_____

Date

■ FORM C:
CERTIFICATION REPORT

Please certify to your most recent fiscal year sales level.

For All Manufacturers:
Fee for the primary (LIC assigned) is computed on the principle of gross sales to the health care industry. In calculating sales, include sales of all divisions and sales to other manufacturers, but do not include intracompany sales.

For All Distributors/Wholesalers:
Fee for the primary (LIC assigned) is computed on the principle gross sales of private labeled packaged products.

THIS INFORMATION WILL BE TREATED ON A CONFIDENTIAL BASIS

Specify annual sales $_____Fiscal year of specified sales: _____year.

Check the appropriate box and enter BASE FEE amount on line (1) Of LABELER FEES from FORM B.

SALES	BASE FEE FOR PRIMARY LIC	SALES	BASE FEE FOR PRIMARY LIC
❒ to $2 million	$500	❒ to $100 million	$7,500
❒ to $5 million	$1,250	❒ to $150 million	$9,000
❒ to $10 million	$2,500	❒ to $500 million	$12,000
❒ to $30 million	$4,000	❒ above $500 million	$20,000
❒ to $60 million	$5,000		

By signing below I certify sales specified and category indicated to be correct and in accordance with the guidelines stated above.

_____
Signature of Official Representative Title

_____
Date

ANSI/HIBC 2.3

THE HEALTH INDUSTRY BAR CODE (HIBC) SUPPLIER LABELING STANDARD

An American National Standard (ANS)

Secretariat:
Health Industry Business Communications Council
2525 E. Arizona Biltmore Circle, Suite 127
Phoenix, Arizona 85016

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THE HEALTH INDUSTRY BAR CODE (HIBC)
SUPPLIER LABELING STANDARD

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HIBC Standards are supported globally via an international network of HIBCC affiliate offices, and by other organizations listed below. HIBC Standards are developed in accordance with the procedures of the American National Standards Institute (ANSI) and in consultation with our affiliates and other interested parties.

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* When calling from within the U.S., you must first dial 011.

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Foreword

Automatic identification technology is continually evolving. As technological advances prove applicable to the health care industry, they will be incorporated into revisions of this standard, wherever possible. However, every attempt will be made to maintain the existing data structures, thereby allowing new technology to be introduced into systems in a non-disruptive manner. HIBCC recognizes that this standard is a technology driven solution to improvement of health care delivery. As new technology becomes widely available, the standard will be modified to incorporate the advantages of the new technologies. References to other and symbol formats have been updated to reflect current usage.

1.0 Scope

This document describes the voluntary HIBC Supplier Labeling Standard for products distributed within the health care industry. Labelers (manufacturers) of health care products are strongly encouraged to identify their products with consistently readable symbols in accordance with the standards described herein. For additional labeling guidance sources, see the organizations listed in Appendix D, “Reference Definitions”.

1.1 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols

ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

ISO/IEC 15418 Information technology -- EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance

ISO/IEC 15434 Information technology — Automatic identification and data capture techniques — Syntax for high-capacity ADC media

ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification

ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code 2005 bar code symbology specification

ISO/IEC 24728 Information technology -- Automatic identification and data capture techniques -- MicroPDF417 bar code symbology specification

ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification

The above International Standards can be obtained at either http://www.ansi.org or http://www.iso.org

1.2 Symbol Quality Compliance and Printing Assistance

Printed bar code symbols must meet or exceed the quality requirements of Section 5 and be easily scannable by standard bar code scanners at the point of use. Labelers having questions about or problems meeting the requirements of this standard should contact HIBCC in Phoenix at (602) 381-1091 or one of the international offices.

2.0 Supplier Labeling Data Structures

It is intended that all health care products be labeled with a Primary Symbol, which identifies the labeler, the product code, and the unit of measure. Secondary information is useful to distributors and providers and, at the discretion of the labeler, should be added.

2.1 Primary Data Structure

The primary data structure contains an indication of the labeler of the item, the item, the packaging level, and a Check Character. Once constructed from these four elements, these structures should not be parsed. The labeler identification is a data element that is controlled by either the Health Industry Business Communications Council (HIBCC), or by other international organizations. A labeler that chooses to utilize the HIBC Labeler Identification Code (LIC) should follow the HIBC LIC data and symbology format.

2.1.1 HIBC LIC Primary Data Structure

The HIBC LIC Primary Data Structure format encodes a "+" identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single-digit Check Character (C).

The format for the Primary Data Structure format follows (for illustration purposes, the product identifier, or PCN, is shown at its maximum length, 18 characters, therefore the maximum symbol length is 25 characters): See Table 1

+ I I I I P P P P P P P P P P P P P P P P P U C

where: (see below)

Table 1

Field Descriptor	Field Length	(F)ixed Length (V)ariable Length	Field Description
+	1	F	HIBC Supplier Labeling Flag Character "+"
I	4	F	Labeler Identification Code (LIC) an alphanumeric number, with the first character always being alphabetic.
P	1-18	V	Labelers Product or Catalog Number (PCN). Alphanumeric data
U	1	F	Unit of Measure ID, Numeric value only, 0 through 9, where 0 is for unit-of use items.1 to 8 are used to indicate different packaging levels above the unit of use. The value 9 is used for variable quantity containers when manual key entry or scan of a secondary will be used to collect specific quantity data. The labeler should ensure consistency in this field within their packaging process.
C	1	F	Check Character calculated from the above characters. (see Appendix B2)

The Labeler Identification Code (LIC) will be assigned and maintained by HIBCC. The first character of this field will always be an alphabetic character. The LIC may identify a labeler to the point of separate subsidiaries and divisions within a parent organization.

The Product or Catalog Number (PCN) shall be compressed to eliminate embedded spaces and special characters. Special characters shall not be used in this field. Examples of this compression follow:

655-9 ..... would become 6559
24-86-2S ..... would become 24862S
84/XPG ..... would become 84XPG
MP 15 86-G……..would become MP1586G
92.885*BK ..... would become 92885BK

This compression impacts only the machine-readable representations of the PCN and its associated human readable interpretations. Other external package markings and catalog listings covered by this standard remain the prerogative of the individual labeler.

The Unit of Measure Identifier (U/M) is a numeric representation of the relative level of packaging (0 to 9) with 0 being the lowest level or “unit-of-use”. For example, a labeler might pack unit-of-use items in a box, boxes in a carton, and cartons in a case. One way of labeling this example would be, unit-of-use = 0; Box = 1; Carton = 3; and Case = 5. It may be that a unit-of-use is packaged, however, in a box. For instance, individual cotton swabs would be considered the unit-of-use and may go unmarked. Consequently, the box in which the cotton swabs were packaged would be marked with the HIBC Supplier Primary Data Structure with a 1 or greater in the U/M field. Note that U/M identifiers are arbitrarily assigned by each labeler and must be internally consistent.

2.1.2 Primary Data Structure in Electronic Data Interchange

For information about communicating Primary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database. See Appendix B.2.1.

2.2 Secondary Data Structure

Optional secondary data elements are used in conjunction with primary data elements to encode quantity and/or expiration date (or expiry date) and/or Lot/Batch/Serial Number. Appendices E and F describe the secondary data fields in detail.

2.2.1 HIBC LIC Secondary Data Structure

The format for the HIBC Secondary Data Structure, whose maximum length is 39 characters, is shown in Table 2.

Table 2

Field Descriptor	Field Length	Field Description
+	1	HIBC Supplier Labeling Flag Character, "+"
R	1, 2 , 3, or 5	Quantity/Date/Lot or Serial Number Reference Identifier Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No quantity or Lot/Batch or Serial Number is present. $: If the first character is a "$" and the second character is alphanumeric, then the Quantity and Date fields are not used. $$: If the first two characters are "$$" followed by a digit, then the digit specifies quantity and Date Field format. For use with lot numbers, not serial numbers. $$+: If the first three characters are "$$+" followed by digit, then the digit specifies quantity and date field format. For use with serial numbers, not lot numbers. See Appendix E1.2
Q	0,3, or 6	Quantity Field, format indicator followed by two-digit or five-digit quantity, for use after the Reference Identifier.
D	0 or 4-9	Expiration Date Field, for use after the Reference Identifier (includes the date field format indicator).
B	0-18	Lot/Batch **or** Serial Number Field, Alphanumeric field. See Appendix E1.2
L	1	Link Character (Check Character from primary data field.) (See 2.2.1.1 for concatenation rule).
C	1	Modulo 43 Check Character (calculated from the above characters) See Appendix B2.0.

Note: The HIBC Secondary Data Structure is distinguished from the Primary Data Structure in that the Primary Data Structure has an alphabetic character following the HIBC Supplier Labeling Flag Character "+",while the Secondary Data Structure has a numeric character or a "$" following the HIBC Supplier Labeling Flag Character. See Appendices E and F for more information.

2.2.1.1 Combining Primary and Secondary Codes in One Symbol when Using the HIBC LIC Format

When combining the Primary and Secondary Code into a single symbol (known as concatenation), a forward slash (/) is used as a delimiter between the primary and secondary data. In addition, the primary data Link Character, the plus (+) at the start of the secondary data, and the secondary data Link Character will be omitted. Only one Check Character at the end of the symbol will be used which will check the entire symbol.

For example:
+ A 9 9 9 1 2 3 4 5 / $ $ 5 9 9 0 1 5 1 0 X 3 J
Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
99015	Expiration Date is 15 day of year 1999 (15 January 1999) in the YYJJJ format (Julian Date format)
10X3	Lot Number
J	J is the Check Character

2.2.2 GS1 Secondary Data Structures

The GS1 General Specifications describe secondary data structures through the use of Application Identifiers (AI's). HIBCC recognizes that two of these formats have been used in health care settings. They are AI (22) – secondary data for the health industry and AI (240) - additional product identification assigned by the manufacturer. The use of any secondary data structure is optional and used at the discretion of the labeler. According to the GS1 General Specifications, the use of AI (22) is no longer recommended.

2.2.3 Secondary Data Structure in Electronic Data Interchange

For information about communicating Secondary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database. See Appendix B.2.1.

3.0 Label Symbologies

It is possible for a Primary (or a Primary and Secondary) Label to be encoded in one of two possible linear bar code symbologies, or alternatively in one of the approved 2D symbologies.

No special characters (-, ., $, /, +, %, and space) are used other than the use of the flag characters, "+" and "$", in the beginning of the HIBC LIC symbols. Note that the generated Check Character may, however, be one of these special characters, including space. In addition, when combining both Primary and Secondary information in a single barcode, the "/" character is used as a concatenation character. (See section 2.2.1.1 for use).

The data structure and human-readable interpretation is identical regardless of symbology used.

See Appendix C for detailed printing information.

Specifications for these symbologies are available http://www.ansi.org and http://www.iso.org .

3.1 HIBC LIC Primary and/or Secondary Data – Linear Symbologies

Where a labeler decides to use a linear symbology, the labeler may use any one of the linear symbologies in this section as directed.

- **Code 128:** HIBC primary and secondary data should be printed in separate Code 128 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification.*

- **Code 39**: HIBC primary and secondary data should be printed in separate Code 39 symbols but may be concatenated if space allows. More information on this symbology may be obtained *from ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification.*

If Code 39 is used, the Regular setting (not Full ASCII) should be used. In addition, the full ASCII function shall be disabled in the reader. The wide to narrow ratio should be 3:1, the inter-character gap should be equal to the nominal narrow element dimension (X-dimension) and the Mod 43 symbology Check Character is used.

3.2 HIBC LIC Primary and/or Secondary Data – 2D Symbologies

Where a labeler decides to use a 2D symbology, the labeler may use any one of the 2D symbologies in this section as directed. When using a 2D symbol, a single 2D code should be used to carry all Primary HIBC data (or if required, Primary and Secondary HIBC data). That is, those requiring the use of Primary and Secondary data structures should concatenate both into a single 2D code (See section 2.2.1.1 for concatenation mechanism). The labeler may also use **ISO/IEC 15434** in a 2D symbol, as described in section 8.0.

- **Aztec Code:** HIBC data should be printed in a single Aztec Code symbol. More information on this symbology may be obtained from *ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification.*

- **Data Matrix ECC200:** HIBC data should be printed in a single Data Matrix ECC200 symbol. More information on this symbology may be obtained from *ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification,*

- **MicroPDF417:** HIBC data should be printed in a single MicroPDF417 symbol. More information on this symbology may be obtained from *ISO/IEC 24728 "Information Technology, Automatic Identification and Data Capture Techniques - Bar Code Symbology Specification - MicroPDF417"*

- **QR Code 2005:** HIBC data should be printed in a single QR Code 2005 symbol. More information on this symbology may be obtained *from ISO/IEC 18004:2006 Information technology -- Automatic identification and data capture techniques -- QR Code 2005 bar code symbology specification*

4.0 Label Features

HIBC Guidelines provide information on printing techniques, symbol placement, and symbol orientation.

See Section 5 for print quality requirements and Appendix C for specific 2D symbol rules, guidance and examples

4.1 Human-Readable Interpretation

All legally required marking shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

The following are meant as guidance, and in no case are to be meant to replace appropriate regulations.

The preferred human-readable interpretation of a HIBC Supplier Labeling linear Symbol is a line of characters, preferably directly underneath the bar code symbol, representing all encoded characters. The human-readable interpretation is intended to be used for human recognition only, and not as a method of machine readability addressed in this standard.

It is the recommendation of HIBCC that the human-readable interpretation of zero be represented as “Ø”. The Check Character or Link Character in the symbol will sometimes be a space character. In this case, the human-readable interpretation shall use an “underscore” to represent the space character. See Appendix B.2.1 for further guidance.

While the asterisk, “*” is not encoded within the barcode symbols, the human-readable interpretation for both HIBC LIC Primary and Secondary linear symbols should be bounded in the beginning and at the end of the data string by an asterisk, “*”.

The recommended human-readable format for the HIBC LIC Primary and Secondary linear Symbol, always enclosing the human-readable data with the “*” regardless of symbology, should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

See Appendix H

4.2 Label Placement

Transport package labels should be placed no closer than 1.25 inches (3.2 cm) from any package edge, and the bottom edge of the label should be within the range of 1.25 inches to 3.0 inches (3.2 cm to 7.6 cm) from the natural bottom of the package. For more information about transport package labels, consult ANSI MH10.8.1, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications". For inner package guidance, consult the HDMA document “HDMA Numerical and Automatic Identification of Drug Products”.

4.3 Bar Code Symbol Examples

Examples of formats and printed symbols are shown below

4.3.1 HIBC LIC Primary Data Structure

Shown below are the symbols for the HIBC LIC Primary Data Structure.

Figure 1. Code 128
Note: the figures in this document are here as examples only, and due to the nature of the document their resolution may not conform to the specifications that are needed when using these symbols in a working environment

Figure 2. Code 39

1.69” wide, 0.2” high, 6.7 mil X-dimension

Figure 3 Code 128

4.3.2 HIBC LIC Secondary Data Structure

Shown below are the symbols for the HIBC LIC Secondary Code Data Structure. They are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 3) is G, and the Check character in the example below is %.

+83278F8G9H0J2G%

Figure 5. Code 128

+83278F8G9H0J2G%

Figure 6. Code 39

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol

***+A99912345/**
$$59901510X3J*

5.0 Print Quality

5.1 Code 128 or Code 39

The bar code symbol quality for a Code 128 or Code 39 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Over time, most labelers have used an X-dimension of 0.010 inches (0.25 mm). More recently, those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm).

Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

5.2 Aztec Code, Data Matrix or QR Code

The bar code symbol quality for an Aztec Code, Data Matrix or QR Code symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.010 inches (0.25 mm). Any X-dimension greater than 0.010 inches is allowable if the print quality requirement is met.

5.3 MicroPDF417

The bar code symbol quality for a MicroPDF417 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols.*
Labelers should attempt to reach B/06/660 or better at the time of printing.

Those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm). Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be equal to two times the X-dimension. Quiet Zones should be at least two times the X-dimension.

6.0 Unique Transport Unit ID

Shipping containers (Unit Loads and Transport Packages) may be identified by a symbol that carries the Unique Transport Unit Identifier. The Unique Transport Unit Identifier shall be the unique transport unit identifier using the American National Standard ANS MH10.8.2-2006 Data Identifier and Application Identifier Standard, Data Identifier "J" represented in either Code 128 or Code 39. (This method may be used by HIBC-LIC labelers).

See Appendix G on the Unique Transport Unit ID Label for detailed information.

For more information about transport package labels, consult ANSI MH10.8.2, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

7.0 Radio Frequency Identification (RFID)

HIBCC has produced a Guideline for RFID – *Using HIBC Standards with RFID: An Implementation Guideline V1.2007* - which is a specification of the coding schemas required for RFID tagging using the HIBCC standards. This guideline is available from HIBCC, and can be downloaded from the HIBCC website www.hibcc.org.

8.0 Using Data Identifiers (DI's) with HIBC LIC for 2D barcodes

Suppliers may wish to use the message format defined in ISO/IEC 15434 with Data Identifiers (DI's) for creating 2D symbols. This may apply to small packages where the label is small, and insufficient for the inclusion of a linear 1D barcode. It may also apply to suppliers who wish to include other data in the symbol otherwise not available by using this standard. For example, a manufacturer may wish to include separately the production date and the expiry date for a product.

8.1 Issuing Agency Code

When using the HIBCC LIC with DI's, it is important that the Issuing Agency Code (IAC) for HIBCC is used. This identifies the code that follows as a unique identifier structured in accordance with the HIBC LIC. Cross enterprise and cross country uniqueness is specified by ISO/IEC 15459. This standard regulates the responsibility for the issuing of unique codes. Organizations wishing to be registered as Issuing Agencies are required to apply for a registration with the Netherlands Normalization Institute (NNI), which has been authorized by CEN and ISO to register organizations under ISO/IEC 15459. NNI assigns "Issuing Agency Codes" (IAC) to organizations which qualify to be registered as an authorized Issuing Agency.

HIBCC has successfully applied to be a registered Issuing Agency. The Issuing Agency Code assigned to HIBCC is the characters "RH".

EHIBCC (The European HIBCC organization) has successfully applied to be a registered Issuing Agency. The Issuing Agency Code assigned to EHIBCC is the characters "LH".

Other Issuing Agencies authorized under ISO/IEC 15459 include:

Table 3 – Example Issuing Agency Codes

Issuing Agency Code	Issuing Agency	Enterprise Identifier
0-9	GS1 (formerly EAN-UCC)	GS1
LB	Telcordia Technologies, Inc	ANSI T1.220
UN	Dun & Bradstreet	DUNS
D	Allied Committee 135	CAGE
LH	European Health Industry Business Communications Council	EHIBCC
RH	Health Industry Business Communications Council	HIBCC
LD	Department of Defense	DODAAC

The full list of IAC's can be accessed from http://www2.nen.nl/getfile?docName=196579

8.2 Message Envelope

ISO/IEC 15434 defines a message envelope which included a header that allows a system to distinguish symbols following the standard. In addition, the envelope allows mixing DIs with other data systems. The message header is "[ ) > Rs 0 6 Gs". The individual DIs are separated by a Gs character and the message is terminated with the two characters Rs EoT.

Note: The ASCII value in decimal for Gs is 29, Rs is 30 and EoT is 4.

8.3 Human Readable Interpretation

When using ISO/IEC 15434 data structures, the "*" is not used to bound the human readable interpretation (HRI) and the HIBC check character is not encoded.

While the use of HRI is optional, it may not be possible to fit on a package with some sets of data.

When used, a useful convention is to include the DI in parentheses. This allows easy identification of the data and the ability to concatenate without ambiguity.

When HRI is used, the message envelope characters encoded in the symbol (header, delimiter and trailer) are not shown.

In the examples below various arrangements of HRI are shown to demonstrate some of the possible options.

8.4 Example Using ISO/IEC 15434 and Data Identifiers with HIBC LIC

(25P)RHB1231234560(26Q)0(1T)L123(16D)20071217(14D)20200131

The above Datamatrix symbol is encoded with the data string as shown. The data defined in this string is as shown in the Table 4 below:

Table 4

[ )>Rs06Gs	Message header
25P	Data Identifier for a supplier assigned part number, prefixed by a two segment identification of that supplier. The first segment is the unique issuing agency code ('RH' or 'LH' from Table 3 above). The second segment is the HIBCC supplier LIC. (see http://www.nen.nl/nl/pro/line/ISOIEC15459_and_EN1572_guide.html),
RH	The Issuing Agency Code (IAC) for HIBCC
B123	The Supplier LIC
1234560	The part number
Gs	Data delimiter
26Q	Packaging Level DI
0	Packaging Level Indicator
Gs	Data delimiter
1T	Data Identifier for Lot Number assigned by Supplier
L123	Lot Number
Gs	Data delimiter
16D	Data Identifier for Production date formatted as YYYYMMDD
20071217	Data representing the date: 17 December 2007
Gs	Data delimiter

14D	Data Identifier for Expiry Date formatted as YYYYMMDD
20200131	Data representing the date: 31 January 2020
RsEoT	Message trailer

Using ISO/IEC 15434, it is also possible to code a globally unique serial number as in the example below:

(25S)LHB123S123456789

The data defined in this string is as shown in the Table 5 below:

Table 5

[ )>Rs06Gs	Message header
25S	Data Identifier for a supplier assigned serial number, prefixed by a two segment identification of that supplier. The first segment is the unique issuing agency code ('RH' or 'LH' from Table 3 above). The second segment is the HIBCC supplier LIC. (see http://www.nen.nl/nl/pro/line/ISOIEC15459_and_EN1572_guide.html),
LH	The Issuing Agency Code (IAC) for EHIBCC
B123	The Supplier LIC
S123456789	The Supplier Assigned Serial Number for the item
RsEoT	Message trailer

Using ISO/IEC 15434, it is possible to code the Lot Number and Serial Number in the same symbol as shown below:

(25P)RHB123123456

(26Q)0(1T)L123

(S)123456789

The data defined in this string is as shown in the Table 6 below:

Table 6

[ )>Rs06Gs	Message header
25P	Data Identifier for a supplier assigned part number, prefixed by a two segment identification of that supplier. The first segment is the unique issuing agency code ('RH' or 'LH' from Table 3 above). The second segment is the HIBCC supplier LIC. (see http://www.nen.nl/nl/pro/line/ISOIEC15459_and_EN1572_guide.html),
RH	The Issuing Agency Code (IAC) for HIBCC
B123	The Supplier LIC
123456	The part number

Gs	Data delimiter
26Q	Packaging Level DI
0	Packaging Level Indicator
Gs	Data delimiter
1T	Data Identifier for Lot Number assigned by Supplier
L123	Lot Number
Gs	Data delimiter
S	Data Identifier for Serial Number
123456789	Data representing the Serial Number for the item
RsEoT	Message trailer

Appendix A – Julian Calendar

Table A1

DAY OF MONTH	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	001	032	060	091	121	152	182	213	244	274	305	335
2	002	033	061	092	122	153	183	214	245	275	306	336
3	003	034	062	093	123	154	184	215	246	276	307	337
4	004	035	063	094	124	155	185	216	247	277	308	338
5	005	036	064	095	125	156	186	217	248	278	309	339
6	006	037	065	096	126	157	187	218	249	279	310	340
7	007	038	066	097	127	158	188	219	250	280	311	341
8	008	039	067	098	128	159	189	220	251	281	312	342
9	009	040	068	099	129	160	190	221	252	282	313	343
10	010	041	069	100	130	161	191	222	253	283	314	344
11	011	042	070	101	131	162	192	223	254	284	315	345
12	012	043	071	102	132	163	193	224	255	285	316	346
13	013	044	072	103	133	164	194	225	256	286	317	347
14	014	045	073	104	134	165	195	226	257	287	318	348
15	015	046	074	105	135	166	196	227	258	288	319	349
16	016	047	075	106	136	167	197	228	259	289	320	350
17	017	048	076	107	137	168	198	229	260	290	321	351
18	018	049	077	108	138	169	199	230	261	291	322	352
19	019	050	078	109	139	170	200	231	262	292	323	353
20	020	051	079	110	140	171	201	232	263	293	324	354
21	021	052	080	111	141	172	202	233	264	294	325	355
22	022	053	081	112	142	173	203	234	265	295	326	356
23	023	054	082	113	143	174	204	235	266	296	327	357
24	024	055	083	114	144	175	205	236	267	297	328	358
25	025	056	084	115	145	176	206	237	268	298	329	359
26	026	057	085	116	146	177	207	238	269	299	330	360
27	027	058	086	117	147	178	208	239	270	300	331	361
28	028	059	087	118	148	179	209	240	271	301	332	362
29	029	*	088	119	149	180	210	241	272	302	333	363
30	030		089	120	150	181	211	242	273	303	334	364
31	031		090		151		212	243		304		365

The HIBC Supplier Labeling Standard Format for use of Julian dating includes the last two digits of the year followed by a three-digit day-of-the-year code. For example, November 7, 1994 is represented as “94311” (the 311th day of 1994).

*A leap year has 366 days with February having 29. Julian dating in leap years is the same through February 28 (059) with February 29 as 060. All dating from March 1 through December 31 is incremented by one during leap years.

Appendix B – Check Character Calculations

B.1.0 Check Character Calculations

Be sure to use the Modulo 43 calculation when using the HIBC LIC data structures, whether Code 39 or Code 128 is used.

B.2.0 HIBC LIC Check Character Modulo 43 Generator

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Supplier Labeling Data Structure: + A 1 2 3 B J C 5 D 6 E 7 1
Sum of values: 41+10+1+2+3+11+19+12+5+13+6+14+7+1 = 145

Divide 145 by 43. The quotient is 3 with a remainder of 16. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 16, or "G". The complete Supplier Labeling Data Structure, including the Check Character, would therefore be:

+ A 1 2 3 B J C 5 D 6 E 7 1 G

Table of numerical value assignments for computing the HIBC LIC data format Check Character

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

B.2.1 Space Character Caution

The HIBC-LIC Check/Link character is **not** part of the **data message.** As such it should not normally be stored in a database or transmitted via EDI. It should be stripped away after the check and link functions have been executed. One of the possible values of the Check/Link Character is a space character (value 38). Although not recommended, if the link character must be stored or transmitted, the space character should be stored or transmitted explicitly as ASCII decimal 32 (ASCII Hex '20'). Note that some legacy systems and or software are unable to receive and or interpret trailing spaces as part of a data message.

Appendix C – 2D Symbol Considerations

C.1 2D Symbols

Specifications for Aztec code, Data Matrix ECC200, MicroPDF417 and QR Code 2005 are available from http://www.ansi.org and http://www.iso.org

See section 3.3 for rules when using a 2D symbol.

C.2 Human-Readable Interpretation/Regulatory Data

All legally required marking shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

Where space allows, the human readable interpretation should accompany the symbol.

C.3 Label Placement/Descriptive Data

For more information about transport package labels, consult ANSI MH10.8.1, *"For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications".* For inner package guidance, consult the HDMA document *"HDMA Numerical and Automatic Identification of Drug Products".*

Any item descriptive data and or graphics is allowed provided it is printed in an area which does not intrude into the symbol region, including quiet zones, and does not affect the scannability of the symbol.

C.4 Printing Plates

Often, source printing requires the generation of a printing plate. Care should be given to produce the printing plate with smaller bars to compensate for ink spread. When "bar width reduction" or "X-dimension width reduction" is implemented, be sure that the spaces are enlarged by the same amount that the bars are reduced. The print quality requirement must be met on the final printed symbol. The printing plate can be fabricated using any method or accuracy as long as the final printed symbol meets the above specification.

C.5 Scanning Considerations

Scanners have different capabilities, be sure to match your scanner with your proposed symbol.

C.6 Example Symbols - Primary Data Structure

Example Data Structure:

+H123ABC01234567890D

Aztec Code

0.19" wide, 0.19" high
10 mil cell size, 19 x 19 matrix

Figure C1 Aztec Code

Data Matrix ECC200

0.18" wide, 0.18" high
10 mil cell size, 18 X 18 matrix

Figure C2 Data Matrix ECC200

MicroPDF417 (minimum height configuration)

0.66" wide, 0.16" high,
6.7 mil X-dimension, 2:1 Y:X ratio
4 columns x 8 rows

Figure C3 MicroPDF417

MicroPDF417 (minimum width configuration)

0.25" wide, 0.56" high
6.7 mil X-dimension, 2:1 Y:X ratio
1 column x 28 rows

Figure C4 MicroPDF417 (minimum width configuration)

QR Code 2005

0.21" wide, 0.21" high
10 mil cell size, 21 X 21 matrix

Figure C5 QR Code 2005

Appendix D – Reference Definitions

For the purposes of printing the HIBC Supplier Labeling Symbol, the following informative definitions are included for convenience.

D.1 AIM DPM Quality Guideline
AIM document detailing best practice methods to obtain and regulate quality of Direct Part Mark techniques.

D.2 Aztec Code
Aztec Code is a two-dimensional matrix style bar code symbology. Refer to ISO/IEC 24778.

D.3 Bars
The black or darker areas of the bar code symbol.

D.4 Code 128
A bar code pattern for alphanumeric data ideally suited to represent long strings of numeric digits with very high reading security. See ISO/IEC 15417.

D.5 Code 39
A bar code pattern for alphanumeric data ideally suited to printing processes that print one character at a time. When used with the symbology Check Character, Code 39 provides very high reading security. See ISO/IEC 16388.

D.6 Data Matrix
Data Matrix code is a two-dimensional matrix style bar code symbology that may be arranged in either a square or rectangular pattern. Refer to ISO/IEC 16022.

D.7 EHIBCC
EHIBCC (European Health Industry Business Communications Council) is an organization established in Brussels, Belgium for administration of the Health Industry Bar Code (HIBC) Supplier Labeling Standard. It is located at Jozef Israelaan 3, 2596 AM The Hague, The Netherlands. The telephone number for EHIBCC is 011-31-70-3244754 and the Fax number is 011-31-70-324-2522. Web site: www.ehibcc.com

D.8 GS1 (formerly EAN-UCC)
GS1 (formerly EAN-UCC) develops and maintains standards for article numbering, bar codes and other data carriers, and EDI worldwide. Web site: www.gs1.org

D.9 HDMA (formerly NWDA)
HDMA (Healthcare Distribution Management Association), formerly NWDA, provides guidance on the bar coding of pharmaceutical products. For information contact: HDMA, 901 North Glebe Road, Suite 1000, Arlington, VA 22203. The telephone number is 703-787-0000. Fax: 703-787-6930. Web site: http://www.healthcaredistribution.org/

D.10 HIBC
Health Industry Bar Code.

D.11 HIBCC
HIBCC (Health Industry Business Communications Council) is the organization responsible for the development and maintenance of standards and services for use in the health care industry. HIBCC standards and information on its services, including the HIN System, the UPN Repository and other ecommerce applications are available from HIBCC at: 2525 E Arizona Biltmore Circle, Suite 127, Phoenix, Arizona 85016 or through one of the international offices. The telephone number for HIBCC is 602-381-1091. Fax: 602-381-1093. Email: info@hibcc.org Web site: http://www.hibcc.org.

D.12 HIDA
HIDA (The Health Industry Distributors Association) is an organization that develops and maintains guidelines for medical/surgical products in distribution and patient care. HIDA information is available from The Health Industry Distributors Association, 310 Montgomery St, Alexandria, Virginia 22314. The telephone number is 703-549-4432. Fax 703-549-6495. Web Site: http://www.hida.org.

D.13 ISO Linear Bar Code Print Quality Guideline
ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols should be used for determining print quality and monitoring the printing process for linear symbols.

D.14 NDC
NDC (National Drug Code) is a 10-digit number administered by the FDA, typically for medication. For more information go to http://www.fda.gov/cder/ndc/database/default.htm

D.15 NHRIC
NHRIC (National Health Related Item Code) is a 10-digit number administered by the FDA. For more information go to http://www.fda.gov/cdrh/nhric/nhric.html

D.16 Quiet Zone
An area free of printing, preceding and following all standard bar code symbols, that is required for the decoding process. The quiet zones for Code 128, Code 39, and Interleaved 2 of 5 are at least ten times the X-dimension in size.

D.17 QR Code 2005
A **QR Code 2005** is a two-dimensional matrix style bar code symbology. Refer to ISO/IEC 18004.

D.18 Scannability
A general term describing the property of a bar code symbol whereby an attempt to use bar code reading hardware is successful. Symbols that meet ISO/IEC 15415 and ISO/IEC 15416 with a print quality level of C/06/660 will be scannable with a broad range of hand held bar code reading hardware.

D.19 Spaces
The white or lighter areas of the bar code symbol including the quiet zones.

D.20 Symbology
A set of rules for encoding information in a bar code symbol.

D.21 Two Dimensional Symbol Print Quality Guideline
ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols should be used for determining print quality and monitoring the printing process for 2D symbols.

D.22 Unit-of-Use
A packaging level containing the quantity of the item that is to be administered to a patient in a health care provider facility.

D.23 X-Dimension
The intended width of the narrow bar and narrow space in a bar code symbol.

Appendix E – HIBC Secondary Data Fields

E1.0 HIBC LIC Secondary Data Field

Appendix E describes the Secondary Data Formats with some examples. See Appendix F for a complete listing of Secondary Data Format options.

E1.1 Quantity/Date Fields

These examples are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is "G". Check characters have been calculated for these examples.

Quantity is either a two or five digit field describing the number of units-of-use included in the package identified by the bar code label. The options available for the Quantity and Date Fields are specified by the Quantity/Date/Lot/Serial Number Identifier "R" (see Section 2.2.1) and the first digit of the Quantity and the Date Fields. If the character following the leading "+" is numeric, then the Quantity/Date Identifier Field is null, the Quantity Field is also null and the digit is the first digit in the Julian Date.

For example:

+ 0 4 3 6 6 G X *Date is 12/31/04. The quantity field is null. The lot/batch/serial field is null.*

If the character following the leading "+" is a "$" but the next character is alphanumeric, then both the Quantity and Date Fields are null, and the character following the "$" is the first character in the Lot/Batch Number.

For example:

+ $ A 1 2 3 4 G U *Lot # is A1234*

If there is a two character lot number flag "$$", or a three character serial number flag "$$+", following the leading "+", then the first digit following will specify the Quantity and Date Field formats:

The digits 0 through 7 indicate that the Quantity Field is null and specify the Date Format:

- 0, 1 First digit of month in MMYY (month/year) Date format
- 2 MMDDYY (month/day/year) Date follows
- 3 YYMMDD (year/month/day) Date follows
- 4 YYMMDDHH (year/month/day/hour G.M.T.) Date follows
- 5 YYJJJ (year/Julian day) Date follows
- 6 YYJJJHH (year/Julian day/hour G.M.T.) Date follows
- 7 Date Field is null, Lot Field follows

The digits 8 and 9 specify the Quantity Field format. The first digit following the Quantity Field should be 0 through 7 to define the Date Field format as defined above.

- 8 Two digit Quantity Field follows
- 9 Five digit Quantity Field follows

For example:

+ $ $ 0 9 0 5 A 1 2 3 4 G /	*Date is 9/05 and Lot # is A1234,calculated Check Character is / .*
+ $ $ 8 7 2 4 0 4 1 2 1 5 2 3 G 2	*Quantity is 72 and Date is 12/15/04 23:00 G.M.T., calculated Check Character is 2.*
+ $ $ 9 0 1 4 4 0 7 A 1 2 3 4 G 8	*Quantity is 1440 and Lot # is A1234, calculated Check Character is 8.*

If the Secondary Code specifies only the Quantity, both the Date Field and the Lot/Batch/Serial Number Field should be null, not filled with zeroes, spaces or any other redundant characters, for example:

+ $ $ 8 4 8 G Q *Quantity is 48, calculated Check Character is Q.*

E1.2 Lot/Batch or Serial Number Field

This field can be alphanumeric and vary in length up to a maximum of 18 characters. If the field is not required (because neither Lot/Batch nor Serial Number is desired), the field should be null. The string header +$$ is used for Lot/Batch cases, with the new +$$+ being used exclusively for Serial Number implementations. Note that the 2006 SLS allowed for the creation of Serial Number implementations with the +$$ header. While these will not become invalid, all new implementations should conform to this standard, and existing implementations brought in line with this standard as soon as feasible.

In general, an item will require either a lot/batch number or serial number but not both. Items that require serialization are items such as pacemakers and other such devices that are made up of many components, and where each component itself may come from different lots or batches. At this time, we recommend that any application that needs both be implemented utilizing a 2D barcode and the MH10 nomenclature. (See Section 8.0)

E1.3 Link Character

The Link Character is intended to link the Primary and Secondary Code Data Structures. The Link Character for the Secondary Data Structure is the last character from the Primary Data String in the Primary Symbol (Check Character). If the symbol contains more than one field, the Link Character is still the last character from the first field, i.e. the Primary Data Field.

Appendix F – Data Formats for HIBC Secondary Bar Codes

The following tables show the correct data formats for HIBC secondary bar codes. If a column is left blank, then that information is not used. The following field descriptions are used:

MM	2 digit expiration date month indicator (fixed length of 2 numeric digits)
YY	2 digit expiration date year indicator (fixed length of 2 numeric digits)
DD	2 digit expiration date day indicator (fixed length of 2 numeric digits)
HH	2 digit expiration date hour indicator (fixed length of 2, G.M.T. format)
JJJ	3 digit expiration date Julian Day indicator (fixed length of 3 numeric digits)
LOT	up to 18-digit alpha/numeric lot/batch number
S/N	up to 18-digit alpha/numeric serial number
L	1 digit Link Character
C	1 digit Modulo 43 Check Character
QQ	2 digit quantity (fixed length of 2 numeric digits)
QQQQQ	5 digit quantity (fixed length of 5 numeric digits)

The following example data is always used in the example data section:

Lot Number	3C001
Serial Number	0001
Link Character	L (Check Character from Primary Symbol)
Check Character	C (1 character Modulo 43 Check Character)
Expiration	Date September 28, 2005 at 10 PM
2 digit Qty	24
5 digit Qty	00100

The following secondary data formats can be encoded in either Code 128 or Code 39. As stated before, the link character 'L' is the last character from the primary data string. If the primary message were +A123BJC5D6E71G as in example 4.3.1, the link character 'L' would have a value of 'G'. The Check Character 'C' has not been calculated in these examples.

Table F1

HIBCC Qty Flag	Qty Format Char	Qty Format	Exp Date Flag	Exp Date Format	Lot/Batch Field	Serial Number Field	Link Char	Mod 43 Ck Char	Example Data
+				YYJJJ			L	C	+05271LC
+$					LOT		L	C	+$3C001LC
+$$				MMYY	LOT		L	C	+$$09053C001LC
+$$			2	MMDDYY	LOT		L	C	+$$20928053C001LC
+$$			3	YYMMDD	LOT		L	C	+$$30509283C001LC
+$$			4	YYMMDDHH	LOT		L	C	+$$4050928223C001LC
+$$			5	YYJJJ	LOT		L	C	+$$5052713C001LC
+$$			6	YYJJJHH	LOT		L	C	+$$605271223C001LC
+$$			7		LOT		L	C	+$$73C001LC
+$$	8	QQ		MMYY	LOT		L	C	+$$82409053C001LC
+$$	8	QQ	2	MMDDYY	LOT		L	C	+$$82420928053C001LC
+$$	8	QQ	3	YYMMDD	LOT		L	C	+$$82430509283C001LC
+$$	8	QQ	4	YYMMDDHH	LOT		L	C	+$$8244050928223C001LC
+$$	8	QQ	5	YYJJJ	LOT		L	C	+$$8245052713C001LC
+$$	8	QQ	6	YYJJJHH	LOT		L	C	+$$824605271223C001LC
+$$	8	QQ	7		LOT		L	C	+$$82473C001LC
+$$	8	QQ					L	C	+$$824LC
+$$	9	QQQQQ		MMYY	LOT		L	C	+$$90010009053C001LC
+$$	9	QQQQQ	2	MMDDYY	LOT		L	C	+$$90010020928053C001LC
+$$	9	QQQQQ	3	YYMMDD	LOT		L	C	+$$90010030509283C001LC
+$$	9	QQQQQ	4	YYMMDDHH	LOT		L	C	+$$9001004050928223C001LC
+$$	9	QQQQQ	5	YYJJJ	LOT		L	C	+$$9001005052713C001LC
+$$	9	QQQQQ	6	YYJJJHH	LOT		L	C	+$$900100605271223C001LC
+$$	9	QQQQQ	7		LOT		L	C	+$$90010073C001LC
+$$	9	QQQQQ					L	C	+$$900100LC
+$+						S/N	L	C	+$+0001LC
+$$+				MMYY		S/N	L	C	+$$+09050001LC
+$$+			2	MMDDYY		S/N	L	C	+$$+20928050001LC

+$$+			3	YYMMDD		S/N	L	C	+$$+30509280001LC
+$$+			4	YYMMDDHH		S/N	L	C	+$$+4050928200001LC
+$$+			5	YYJJJ		S/N	L	C	+$$+5052710001LC
+$$+			6	YYJJJHH		S/N	L	C	+$$+605271200001LC
+$$+			7			S/N	L	C	+$$+70001LC

Appendix G - Unique Transport Unit ID Label

G1.0 Unique Transport Unit Identifier

Shipping containers (Unit Loads and Transport Packages) may be identified by a symbol that carries the Unique Transport Unit Identifier.

G1.1 Format Type

The Unique Transport Unit Identifier shall be the unique transport unit identifier using the ANSI MH10.8.2 Data Identifier "J":

G1.2 Scope

HIBC-LIC labeling may use ANS MH10.8.2 Data Identifier "J". See section G2.0 for the data structure of the unique transport unit identifier.

G2.0 Data Structure

The data structure using the ANSI Data Identifier "J" is as follows:

- JLHH123Z987654321, where
- J = ANS MH10.8.2 Data Identifier "J" – Unique Transport Unit Identifier.
- LH = Identifier for the Registration Authority – HIBCC/EHIBCC.
- H123 = HIBCC / EHIBCC Labeler Identification Code.
- 987654321 = Shipper's assigned number for the transport unit. (maximum 13 alphanumeric characters).

G3.0 Symbologies

The Unique Transport Unit Identifier may be represented using Code 128 or Code 39.

G4.0 Unique Transport Unit ID Label Example

Figure G1. Unique Transport Unit ID Label Example

For more information about transport package labeling, consult ANSI MH10.8.1, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

For more information about ANSI Data Identifiers, consult ANSI MH10.8.2, "ANSI Data Identifier Standard", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

Appendix H – Backward Compatibility

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced and were acceptable until April 12, 1997. Among these are the alternate data format identified by "++", the use of stacked symbologies Code 16K and Code 49, and the unit-of-measure convention in the HIBC LIC Primary Symbol. Information about the previous version of this standard is available from HIBCC.

The recommended human-readable format for the HIBC LIC Primary and Secondary Symbol, always enclosing the human-readable data with the "*" regardless of symbology, should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

Appendix I – Bibliography

ISO/IEC 15459-1 Information technology -- Unique identifiers -- Part 1: Unique identifiers for transport units

ISO/IEC 15459-3 Information technology -- Unique identifiers -- Part 3: Common rules for unique identifiers

ISO/IEC 15459-4_Information technology -- Unique identifiers -- Part 4: Individual items

ISO/IEC 15459-6 Information technology -- Unique identifiers -- Part 6: Unique identifier for product groupings

ANS MH10.8.1, For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications

ANS MH10.8.2-2006 American National Standard – Data Identifier and Application Identifier Standard

HDMA Numerical and Automatic Identification of Drug Products, Healthcare Distribution Management Association, 901 North Glebe Road, Suite 1000, Arlington, VA 22203, Phone: 703-787-0000

GS1 General Specifications, see www.gs1.org

Appendix J – Errata

ERRATA #1
to
ANSI/HIBC 2.3-2009
The Health Industry Bar Code (HIBC) Supplier Labeling Standard published 2009

Purpose
The purpose of this errata sheet is to clarify what is currently published. Although not an official part of the standard, the committee approved the following and intends to add these errata items to the next full revision of the American National Standard.

Shaded text indicates editorial additions or modifications to wording:

Page	Erratum
9	Table 2, row 2, column 3, second paragraph, add an asterisk to the end of the sentence: “Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No quantity or Lot/Batch or Serial Number is present.*”
9	Add the following text outside and at the bottom of Table 2: “* Note: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5".”
29	Section E1.1 Quantity/Date Fields, add “(See Annex F)” to the end of the second paragraph: “Quantity is either a two or five digit field describing the number of units-of-use included in the package identified by the bar code label. The options available for the Quantity and Date Fields are specified by the Quantity/Date/Lot/Serial Number Identifier “R” (see Section 2.2.1) and the first digit of the Quantity and the Date Fields. If the character following the leading “+” is numeric, then the Quantity/Date Identifier Field is null, the Quantity Field is also null and the digit is the first digit in the Julian Date (see Annex F)."
32	Table F1, row 1, column 6: add an asterisk to the empty Lot/Batch Field: “*”
33	Add the following text outside and at the bottom of Table F1: “* Note: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5".”

Subject: Notice of HIBCC Reaccreditation under Revised Procedures
From: James Thompson <Jthompso@ansi.org>
Date: 10/9/2013 12:00 PM
To: Sara Polansky <sjpolan@hibcc.org>

October 9, 2013

Ms. Sara Polansky
Health Industry Business Communications Council
2525 E. Arizona Biltmore Circle
Phoenix, AZ 85016

Dear Ms. Polansky:

On behalf of the Executive Standards Council (ExSC), I am pleased to inform you that the reaccreditation of the **Health Industry Business Communications Council (HIBCC)** under its recently revised operating procedures for documenting consensus on HIBCC-sponsored *American National Standards* has been administratively approved effective **October 9, 2013**. This reaccreditation action relates to the updated version of HIBCC's operating procedures forwarded to my attention today, October 9, 2013. A copy of these procedures will be maintained in HIBCC's accreditation file.

Please be advised that this decision may be appealed in accordance with section 17, *ExSC Hearing of Appeals*, of the *Operating Procedures of the Executive Standards Council*. The ExSC and its Audit Subcommittee reserve the right to request additional changes to HIBCC's accredited procedures as a result of any new procedural requirements issued with future versions of the *ANSI Essential Requirements*, or if any additional instances of non-compliance missed during the current review are later identified during a subsequent audit.

You may download copies of the most recent versions of ANSI's procedural documents and submittal forms from *ANSI Online* at *ANSI Online/ANS Forms* All PINS and BSR-8 forms should be submitted to *ANSI Online* at: http://psawebforms.ansi.org. Completed BSR-9 forms should be submitted to PSA@ANSI.org

You may direct any questions relating to the sale of HIBCC standards on ANSI's Electronic Standards Store (ESS) or ANSI's co-marketing services to Ms. Rosemary Maginniss at 212.642.4885 (rmaginni@ansi.org). Please contact Mr. Bob Hager (212.642.4917; bhager@ansi.org) if you wish to take advantage of ANSI's standards editing services.

If you have any other questions or I can be of further assistance, please do not hesitate to contact me at (212) 642-4913, or via E-mail at jthompso@ansi.org.

Sincerely,

Jim Thompson
Director, Standards Developer & ISO/TAG Accreditation Programs
American National Standards Institute
25 West 43rd Street, 4th Floor
New York, NY 10036
212.642.4913

Hawthorn, Anne T.

From: Hawthorn, Anne T.
Sent: Wednesday, December 04, 2013 11:29 AM
To: 'sjpolan@hibcc.org'
Cc: Fields, Erin
Subject: request for additional information (HIBCC Issuing Agency Application)

Hi Sara

FDA has reviewed HIBCC's application. Please submit the following information so that we may continue our review.

1. On page 49 of your application you define 16D as "Data Identifier for Production date formatted as YYYYMMDD." Please explain whether the Production Date is the Manufacturing Date in this example.

2. Please also indicate whether you will include a Supplemental Serial Number (/S) in your UDIs and, if so, explain how you will include Supplemental Serial Numbers.

3. On page 62, Table F1 you did not include 16D or any reference to the Production or Manufacturing Date. Please explain the discrepancy with page 49 and explain why you did not include 16D. In addition, Table F1 on page 62 does not include the same data delimiters as Table F1 on page 32. Please explain the discrepancy with page 62 and identify the data delimiters you plan to use.

4. On page 39, Table 2 you have used field descriptors rather than the '$$4' type of data delimiters shown in Table F1 on page 62. In addition, it is unclear whether the symbols in Tables 49-51 are data delimiters. Please explain these discrepancies and indicate which data delimiters you plan to use.

5. Identify the ISO standards that your label symbologies and print quality conform with, and define message envelope.

6. Your application refers the ANSI accreditation letter you included to support protections against conflict of interest (COI) between HIBCC (staff and volunteers) and labelers. The ANSI letter is not adequate because it does not address COI. Please describe how HIBCC protects against COI; for example, do you have any required disclosures, standard operating procedures, or terms in your employment or volunteer agreements? FDA encourages you to include any examples of these in your response.

I'm available to discuss any questions you may have.

Anne

Anne T. Hawthorn, JD
Regulatory Policy Analyst (detail)
OSB|CDRH|FDA
WO Bldg 66, Rm 3276
phone 301 796-6561

For more information on UDI and the UDI help desk see www.fda.gov/udi

HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL

December 4, 2013

Anne T. Hawthorne, JD
Regulatory Policy Analyst
OSB / CDRH / FDA
WO Bldg 66, RM 3276
Silver Spring MD 20993

Dear Anne,

In response to your request for additional information, we have provided the following:

1. On page 49 of your application you define 16D as "Data Identifier for Production date formatted as YYYYMMDD." Please explain whether the Production Date is the Manufacturing Date in this example.

Correct, production date and manufacturing date mean the same thing.

2. Please also indicate whether you will include a Supplemental Serial Number (/S) in your UDIs and, if so, explain how you will include Supplemental Serial Numbers.

Yes, we include supplemental serial numbers. These are included in the same way as manufacturing date – i.e. they are added to the secondary string via a delimiter character "/" followed by the DI "S", followed by the serial number.

3. On page 62, Table F1 you did not include 16D or any reference to the Production or Manufacturing Date. Please explain the discrepancy with page 49 and explain why you did not include 16D. In addition, Table F1 on page 62 does not include the same data delimiters as Table F1 on page 32. Please explain the discrepancy with page 62 and identify the data delimiters you plan to use.

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We did not include the supplemental data options in table F1, since they are technically not part of our secondary data format. There are only 2 options for supplemental data – Manufacture date or additional serial number. This has been adequately covered in the text of the standard, without having to further define in table F1. (Please see the attached 2.4 version of the SLS.)

4. On page 39, Table 2 you have used field descriptors rather than the '$$4' type of data delimiters shown in Table F1 on page 62. In addition, it is unclear whether the symbols in Tables 49-51 are data delimiters. Please explain these discrepancies and indicate which data delimiters you plan to use.

In general, the Supplier Labeling Standard (SLS) uses the "/" as the delimiter character. Table 2 on page 39 describes the manner in which data is formatted in the SLS in a general sense. Table F1, on the other hand, defines all the "flags" or Data Identifiers (e.g. $$4) that describe the different formatting options.

Pages 49-51 refer to the MH10 (or ISO 15434) options for coding HIBCC into a Datamatrix symbol. It is an alternative way to use the HIBCC LIC, and not the generally accepted approach.

5. Identify the ISO standards that your label symbologies and print quality conform with, and define message envelope.

ISO/IEC 15416 Information Technology – Automatic identification and data capture techniques – barcode print quality test specification.

The only time that we use a message header and message trailer is when using ISO/IEC 15434 and Data Identifiers (DI's) defined by ANSI MH10, and when coded in a Datamatrix symbol. Under this option, we use the message header "**[)>Rs06Gs**", and the message trailer "**RsEoT**". In between this envelope we use "**Gs**" as the delimiter character to separate out all the data fields, and the ANSI MH10 Data Identifiers (DI's).

6. Your application refers the ANSI accreditation letter you included to support protections against conflict of interest (COI) between HIBCC (staff and volunteers) and labelers. The ANSI letter is not adequate because it does not address COI. Please describe how HIBCC protects against COI; for example, do you have any required disclosures, standard operating procedures, or terms in your employment or volunteer agreements? FDA encourages you to include any examples of these in your response.

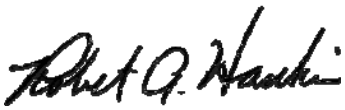
At the beginning of each calendar year, the HIBCC Board of Directors and all volunteer committee members are required to sign a conflict of interest (COI) policy and statement of acceptance, as well as to review our antitrust policy. Our ANSI-related activities are governed by standard operating procedures (SOPs) that are must be

reviewed and approved by ANSI at a minimum of every five years. All HIBCC employees and sub-contractors execute a non-disclosure agreement prior to employment or commencement of work. (Copies of all referenced documents are attached.)

There are no restrictions on who may apply for an LIC, as it is an open standard available to any who chose to use it. Additionally, because the registration process to obtain an LIC assignment requires the labeler to pay only a one-time fee, there are no reoccurring costs, and thus no continuing financial obligations.

We hope that this detail will be sufficient to complete the processing of our application, but please let us know if there are any additional questions.

Thank you for your assistance and best regards,



Robert A Hankin
HIBCC President

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ANSI/HIBC 2.4 - 2013

THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD: FOR PATIENT SAFETY AND UNIQUE DEVICE IDENTIFICATION

(HIBC / SLS / UDI)

HIBCC

Approved American National Standard

ANSI

An American National Standard (ANS)

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THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD:
FOR PATIENT SAFETY &
UNIQUE DEVICE IDENTIFICATION
(HIBC / SLS / UDI)

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Foreword

Automatic identification technology is continually evolving. As technological advances prove applicable to the health care industry, they will be incorporated into revisions of this standard, wherever possible. However, every attempt will be made to maintain the existing data structures, thereby allowing new technology to be introduced into systems in a non-disruptive manner. HIBCC recognizes that this standard is a technology driven solution to improvement of health care delivery. As new technology becomes widely available, the standard will be modified to incorporate the advantages of the new technologies. References to other and symbol formats have been updated to reflect current usage.

1.0 Scope

This document describes the voluntary HIBC Supplier Labeling Standard for products distributed within the health care industry. Labelers (manufacturers) of health care products are strongly encouraged to identify their products with consistently readable symbols in accordance with the standards described herein. For additional labeling guidance sources, see the organizations listed in Appendix D, “Reference Definitions”.

1.1 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols

ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

ISO/IEC 15418 Information technology -- EAN/UCC Application Identifiers and Fact Data Identifiers and Maintenance

ISO/IEC 15434 Information technology — Automatic identification and data capture techniques — Syntax for high-capacity ADC media

ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification

ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification

ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification

The above International Standards can be obtained at either http://www.ansi.org or http://www.iso.org

1.2 Symbol Quality Compliance and Printing Assistance

Printed bar code symbols must meet or exceed the quality requirements of Section 5 and be easily scannable by standard bar code scanners at the point of use. Labelers having questions about or problems meeting the requirements of this standard should contact HIBCC in Phoenix at (602) 381-1091 or one of the international offices.

2.0 Supplier Labeling Data Structures

It is intended that all health care products be labeled with a Primary Symbol, which identifies the labeler in an internationally consistent and unique manner, the product code, and the unit of measure. Secondary information is useful to distributors and providers and, at the discretion of the labeler, should be added.

2.1 Primary Data Structure

The primary data structure contains an indication of the labeler of the item, the item, the packaging level, and a Check Character. Once constructed from these four elements, these structures should not be parsed. The labeler identification is a data element that is controlled by either the Health Industry Business Communications Council (HIBCC), or by other international organizations. A labeler that chooses to utilize the HIBC Labeler Identification Code (LIC) should follow the HIBC LIC data and symbology format.

2.1.1 HIBC LIC Primary Data Structure

The HIBC LIC Primary Data Structure format encodes a "+" identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single-digit Check Character (C).

The format for the Primary Data Structure format follows (for illustration purposes, the product identifier, or PCN, is shown at its maximum length, 18 characters, therefore the maximum symbol length is 25 characters): See Table 1

+ I I I I P P P P P P P P P P P P P P P P P U C

where: (see below)

Table 1

Field Descriptor	Field Length	(F)ixed Length (V)ariable Length	Field Description
+	1	F	HIBC Supplier Labeling Flag Character "+"
I	4	F	Labeler Identification Code (LIC) an alphanumeric number, with the first character always being alphabetic.
P	1-18	V	Labelers Product or Catalog Number (PCN). Alphanumeric data
U	1	F	Unit of Measure ID, Numeric value only, 0 through 9, where 0 is for unit-of use items.1 to 8 are used to indicate different packaging levels above the unit of use. The value 9 is used for variable quantity containers when manual key entry or scan of a secondary will be used to collect specific quantity data. The labeler should ensure consistency in this field within their packaging process.
C	1	F	Check Character calculated from the above characters. (see Appendix B2)

The Labeler Identification Code (LIC) is assigned and maintained by HIBCC. The first character of this field will always be an alphabetic character. The LIC may identify a labeler to the point of separate subsidiaries and divisions within a parent organization.

The Product or Catalog Number (PCN) shall be compressed to eliminate embedded spaces and special characters. Special characters shall not be used in this field. Examples of this compression follow:

655-9 ..... would become 6559
24-86-2S ..... would become 24862S
84/XPG ..... would become 84XPG
MP 15 86-G……..would become MP1586G
92.885*BK ..... would become 92885BK

This compression impacts only the machine-readable representations of the PCN and its associated human readable interpretations. Other external package markings and catalog listings covered by this standard remain the prerogative of the individual labeler.

The Unit of Measure Identifier (U/M) is a numeric representation of the relative level of packaging (0 to 9) with 0 being the lowest level or “unit-of-use”. For example, a labeler might pack unit-of-use items in a box, boxes in a carton, and cartons in a case. One way of labeling this example would be, unit-of-use = 0; Box = 1; Carton = 3; and Case = 5. It may be that a unit-of-use is packaged, however, in a box. For instance, individual cotton swabs would be considered the unit-of-use and may go unmarked. Consequently, the box in which the cotton swabs were packaged would be marked with the HIBC Supplier Primary Data Structure with a 1 or greater in the U/M field. Note that U/M identifiers are arbitrarily assigned by each labeler and must be internally consistent.

2.1.2 Primary Data Structure in Electronic Data Interchange

For information about communicating Primary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database. See Appendix B.2.1.

2.1.3 Reuse of HIBC Primary Identifier

A HIBC Primary Identifier shall not be reissued to any other item, even if the item to which it has been assigned has been discontinued, or superseded by another product.

2.1.4 Definition of the HIBCC Universal Product Number (UPN)

The HIBCC UPN is the Primary Identifier excluding the “+” character and the Check Sum.

2.2 Secondary Data Structure

Optional secondary data elements are used in conjunction with primary data elements to encode quantity and/or expiry date (or expiry date) and/or Lot/Batch/Serial Number. Appendices E and F describe the secondary data fields in detail.

2.2.1 HIBC LIC Secondary Data Structure

The format for the HIBC Secondary Data Structure is shown in Table 2.

Table 2

Field Descriptor	Field Length	Field Description
+	1	Internationally recognized, unique, HIBC Supplier Labeling Data Identifier Flag Character, "+"
R	1, 2 , 3, or 5	Quantity/Date/Lot or Serial Number Reference Identifier Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No quantity or Lot/Batch or Serial Number is present (See Note 2) $: If the first character is a "$" and the second character is alphanumeric, then the Quantity and Date fields are not used. $$: If the first two characters are "$$" followed by a digit, then the digit specifies quantity and Date Field format. For use with lot numbers, not serial numbers. $$+: If the first three characters are "$$+" followed by digit, then the digit specifies quantity and date field format. For use with serial numbers, not lot numbers. See Appendix E1.2
Q	0,3, or 6	Quantity Field, format indicator followed by two-digit or five-digit quantity, for use after the Reference Identifier.
D	0 or 4-9	Expiry Date Field, for use after the Reference Identifier (includes the date field format indicator).
B	0-18	Lot/Batch **or** Serial Number Field, Alphanumeric field. See Appendix E1.2
L	1	Link Character (Check Character from primary data field.) (See 2.2.1.1 for concatenation rule).
C	1	Modulo 43 Check Character (calculated from the above characters) See Appendix B2.0.

Note 1: The HIBC Secondary Data Structure is distinguished from the Primary Data Structure in that the Primary Data Structure has an alphabetic character following the HIBC Supplier Labeling Flag Character "+",while the Secondary Data Structure has a numeric character or a "$" following the HIBC Supplier Labeling Flag Character. See Appendices E and F for more information.

Note 2: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5"."

2.2.1.1 Combining Primary and Secondary Codes in One Symbol when Using the HIBC LIC Format

When combining the Primary and Secondary Code into a single symbol (known as concatenation), a forward slash (/) is used as a delimiter between the primary and secondary data. In addition, the primary data Link Character, the plus (+) at the start of the secondary data, and the secondary data Link Character are omitted. Only one Check Character at the end of the symbol will be used which will check the entire data string.

For example:
+ A 9 9 9 1 2 3 4 5 / $ $ 5 200 0 1 5 1 0 X 3 6
Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
6	6 is the Check Character

2.2.2 Secondary Data Structure in Electronic Data Interchange

For information about communicating Secondary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database. See Appendix B.2.1.

2.3 Additional Supplemental Data

Additional Supplemental Data is optionally added to a combination of a Primary and Secondary data string. Additional Supplemental Data is for use only in the concatenated format and only with 2D symbologies. Additional Supplemental Data can be used when a manufacturer wishes to encode both lot number and serial number in the same symbol and/or date of manufacture.

2.3.1 Data syntax

The Secondary Supplemental Data field is constructed with a "/" character followed by a Data Identifier (DI), followed by data. Multiple Secondary Supplemental data fields are possible. The Secondary Supplemental Data will always follow the Secondary data, and the check character will be inserted at the end of the total string.

2.3.2 Data usage

2.3.2.1 Serial number when Lot number is used

For example, when serial number is encoded with the DI "S" using the following format.

Field Length - an1 + an18 S Serial number or code assigned by the Supplier to an entity for its lifetime, (e.g., computer serial number, traceability number, contract tool identification)

2.3.2.2 Date of Manufacture

Date of Manufacture is encoded with DI “16D” using the following format.

Field Length - an3+n8 16D Production Date (YYYYMMDD) – Date of manufacture

2.3.2 Example of HIBC data string with Secondary Supplemental Data

Following is an example with both a Date of Manufacture and a serial number added to a HIBC Primary and Secondary symbol containing a lot number and an expiry date.

+A99912345/$$52001510X3/16D20111212/S77DEFG451

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111212	December 12, 2011
/	Secondary Supplemental Data delimiter
S	Serial Number Data Identifier
77DEFG45	serial Number
1	1 is the Mod 43 Check Character

3.0 Label Symbologies

It is possible for a Primary (or a Primary and Secondary) Label to be encoded in one of two possible linear bar code symbologies, or alternatively in one of the approved 2D symbologies.

No special characters (-, ., $, /, +, %, and space) are used other than the use of the flag characters, "+" and "$", in the beginning of the HIBC LIC symbols. Note that the generated Check Character may, however, be one of these special characters, including space. In addition, when combining both Primary and Secondary information in a single barcode, the "/" character is used as a concatenation character. (See section 2.2.1.1 for use).

The data structure and human-readable interpretation is identical regardless of symbology used.

See Appendix C for detailed printing information.

Specifications for these symbologies are available http://www.ansi.org and http://www.iso.org .

3.1 HIBC LIC Primary and/or Secondary Data – Linear Symbologies

Where a labeler decides to use a linear symbology, the labeler may use either of the linear symbologies in this section as directed.

- **Code 128:** HIBC primary and secondary data should be printed in separate Code 128 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification.*

- **Code 39**: HIBC primary and secondary data should be printed in separate Code 39 symbols but may be concatenated if space allows. More information on this symbology may be obtained *from ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification.*

If Code 39 is used, the Regular setting (not Full ASCII) should be used. In addition, the full ASCII function shall be disabled in the reader. The wide to narrow ratio should be 3:1, the inter-character gap should be equal to the nominal narrow element dimension (X-dimension) and the optional Mod 43 symbology Check Character is used.

3.2 HIBC LIC Primary and/or Secondary Data – 2D Symbologies

Where a labeler decides to use a 2D symbology, the labeler may use any one of the 2D symbologies in this section as directed. When using a 2D symbol, a single 2D code should be used to carry all Primary, secondary and supplemental HIBC data as required. For example, those requiring the use of Primary and Secondary data structures should concatenate both into a single 2D code (See section 2.2.1.1 for concatenation mechanism). The labeler may also use **ISO/IEC 15434** encoding in a 2D symbol, as described in section 8.0.

- **Aztec Code:** HIBC data should be printed in a single Aztec Code symbol. More information on this symbology may be obtained from *ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification.*

- **Data Matrix ECC200:** HIBC data should be printed in a single Data Matrix ECC200 symbol. More information on this symbology may be obtained from *ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification,*

- **QR Code:** HIBC data should be printed in a single QR Code symbol. More information on this symbology may be obtained *from ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification*

4.0 Label Features

HIBC Guidelines provide information on printing techniques, symbol placement, and symbol orientation.

See Section 5 for print quality requirements and Appendix C for specific 2D symbol rules, guidance and examples

4.1 Human-Readable Interpretation

All product marking including marking required by law shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

The following are meant as guidance, and in no case are to be meant to replace appropriate regulations.

The preferred human-readable interpretation of a HIBC Supplier Labeling linear Symbol is a line of characters, preferably directly underneath the bar code symbol, representing all encoded characters. The human-readable interpretation is intended to be used for human recognition only, and not as a method of machine readability addressed in this standard.

It is the recommendation of HIBCC that the human-readable interpretation of zero be represented as “Ø”. The Check Character or Link Character in the symbol will sometimes be a space character. In this case, the human-readable interpretation shall use an “underscore” to represent the space character. See Appendix B.2.1 for further guidance.

While the asterisk, “*” is not encoded within the barcode symbols, the human-readable interpretation for both HIBC LIC Primary and Secondary linear symbols should be bounded in the beginning and at the end of the data string by an asterisk, “*”.

The recommended human-readable format for the linear HIBC LIC Primary and Secondary Symbol should always enclose the human-readable data with the “*” regardless of symbology and should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

See Appendix H

4.2 Label Placement

Transport package labels should be placed no closer than 1.25 inches (3.2 cm) from any package edge, and the bottom edge of the label should be within the range of 1.25 inches to 3.0 inches (3.2 cm to 7.6 cm) from the natural bottom of the package. For more information about transport package labels, consult ANSI MH10.8.1, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications". For inner package guidance, consult the HDMA document “HDMA Numerical and Automatic Identification of Drug Products”.

4.3 Bar Code Symbol Examples

Examples of formats and printed symbols are shown below

4.3.1 HIBC LIC Primary Data Structure

Shown below are examples of the symbols for the HIBC LIC Primary Data Structure.

+A123BJC5D6E71G

Figure 1. Code 128

Note: the figures in this document are here as examples only, and due to the nature of the document their resolution may not conform to the specifications that are needed when using these symbols in a working environment

+A123BJC5D6E71G

Figure 2. Code 39

1.69” wide, 0.2” high, 6.7 mil X-dimension

+A123BJC5D6E71G

Figure 3 Data Matrix

4.3.2 HIBC LIC Secondary Data Structure

Shown below are examples of the symbols for the HIBC LIC Secondary Code Data Structure. They are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 3) is G, and the Check character in the example below is D.

+$$52001510X3GD

Figure 5. Code 128

+$$52001510X3GD

Figure 6. Code 39

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol

***+A123BJC5D6E71/**
$$52001510X3C*

Note: the 2D concatenated symbol does not contain either check character of the primary symbols but rather has a new check character for the entire data string.

5.0 Print Quality

5.1 Code 128 or Code 39

The bar code symbol quality for a Code 128 or Code 39 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.010 inches (0.25 mm). Those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm) providing the print quality requirements are met.

Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

5.2 Aztec Code, Data Matrix or QR Code

The bar code symbol quality for an Aztec Code, Data Matrix or QR Code symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.015 inches (0.37 mm). Any X-dimension greater than 0.010 (0.25mm) inches is allowable if the print quality requirement is met.

6.0 Unique Transport Unit ID

Shipping containers (Unit Loads and Transport Packages) may be identified by a symbol that carries the Unique Transport Unit Identifier. The Unique Transport Unit Identifier shall be the unique transport unit identifier using the American National Standard ANS MH10.8.2-2006 Data Identifier and Application Identifier Standard, Data Identifier "J" represented in any HIBC symbology. (This method may be used by HIBC-LIC labelers).

See Appendix G on the Unique Transport Unit ID Label for detailed information.

For more information about transport package labels, consult ANSI MH10.8.2, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

7.0 Radio Frequency Identification (RFID)

HIBCC has produced a Guideline for RFID – *Using HIBC Standards with RFID: An Implementation Guideline,* which is a specification of the coding schemas required for RFID tagging using the HIBCC standards. This guideline is available from HIBCC, and can be downloaded from the HIBCC website www.hibcc.org.

8.0 Using Data Identifiers (DI's) with HIBC LIC for 2D barcodes

Suppliers may wish to use the message format defined in ISO/IEC 15434 with Data Identifiers (DI's) for creating 2D symbols. This may apply to small packages where the label is small, and insufficient for the inclusion of a linear 1D barcode. It may also apply to suppliers who wish to include other Data Identifier (DI) data in the symbol. For example, a manufacturer may wish to include storage temperature or a URL.

8.1 Issuing Agency Code

When using the HIBCC LIC with DI's, it is important that the Issuing Agency Code (IAC) for HIBCC is used. This identifies the code that follows as a unique identifier structured in accordance with the HIBC LIC. Cross enterprise and cross country uniqueness is specified by ISO/IEC 15459. This standard regulates the responsibility for the issuing of unique codes. Organizations wishing to be registered as Issuing Agencies are required to apply for a registration with the Netherlands Normalization Institute (NNI), which has been authorized by CEN and ISO to register organizations under ISO/IEC 15459. NNI assigns "Issuing Agency Codes" (IAC) to organizations which qualify to be registered as an authorized Issuing Agency.

HIBCC is a recognized ISO/IEC 15459 registered Issuing Agency. The HIBCC Issuing Agency Code are the characters "RH".

EHIBCC (The European HIBCC organization) has successfully applied to be a registered Issuing Agency. The Issuing Agency Code assigned to EHIBCC is the characters "LH".

8.2 Message Envelope

ISO/IEC 15434 defines a message envelope which includes a header that allows a system to distinguish symbols following the standard. In addition, the envelope allows mixing DIs with other data systems. The message header is "[ ) > Rs 0 6 Gs". The individual DIs are separated by a Gs character and the message is terminated with the two characters Rs EoT.

Note: The ASCII value in decimal for Gs is 29, Rs is 30 and EoT is 4.

8.3 Human Readable Interpretation

When using ISO/IEC 15434 data structures, the "*" is not used to bound the human readable interpretation (HRI) and the HIBC check character is not encoded.

While the use of HRI is optional, it may not be possible to fit a complete HRI on a package with some sets of data.

A useful HRI convention is to include the DI in parentheses. This allows easy identification of concatenated data without ambiguity.

When HRI is used, the message envelope characters encoded in the symbol (header, delimiter and trailer) are not shown.

In the examples below various arrangements of HRI are shown to demonstrate some of the possible options.

8.4 Example Using ISO/IEC 15434 and Data Identifiers with HIBC LIC

(25P)RHA1991234(26Q)5(1T)10X3(16D)20111212(14D)20200115(S)77DEFG45(2E)6(33L)www.hibcc.org

The above Datamatrix symbol is encoded with the data string as shown in Table 4 below:

Table 4

[ )>Rs06Gs	Message header
25P	Data Identifier for a supplier assigned part number, prefixed by a two segment identification of that supplier. The first segment is the unique issuing agency code ('RH' or 'LH' from Table 3 above). The second segment is the HIBCC supplier LIC. (see http://www.nen.nl/nl/pro/line/ISOIEC15459_and_EN1572_guide.html),
RH	The Issuing Agency Code (IAC) for HIBCC
A199	The Supplier LIC
1234	The part number
Gs	Data delimiter
26Q	Packaging Level DI
5	Packaging Level Indicator
Gs	Data delimiter
1T	Data Identifier for Lot Number assigned by Supplier
L123	Lot Number
Gs	Data delimiter
16D	Data Identifier for Production date formatted as YYYYMMDD
20111212	Data representing the date: 12 December 2011
Gs	Data delimiter
14D	Data Identifier for Expiry Date formatted as YYYYMMDD
20200115	Data representing the date: 15 January 2020
Gs	Data delimiter
S	Serial Number
77DEFG45	Data representing Serial Number
Gs	Data delimiter
2E	Maximum allowed temperature
6	Temperature in degrees celsius

Gs	Data delimiter
33L	Uniform Resource Locator (URL)
www.hibcc.org	The URL for the Health Industry Business Communications Council
RsEoT	Message trailer

Using ISO/IEC 15434, it is also possible to encode a globally unique serial number as in the example below:

(25S)LHB123S123456789

The data defined in this string is as shown in the Table 5 below:

Table 5

[ )>Rs06Gs	Message header
25S	Data Identifier for a supplier assigned serial number, prefixed by a two segment identification of that supplier. The first segment is the unique issuing agency code ('RH' or 'LH' from Table 3 above). The second segment is the HIBCC supplier LIC. (see http://www.nen.nl/nl/pro/line/ISOIEC15459_and_EN1572_guide.html),
LH	The Issuing Agency Code (IAC) for EHIBCC
B123	The Supplier LIC
S123456789	The Supplier Assigned Serial Number for the item
RsEoT	Message trailer

Note: This example is particularly well suited for Direct Part Marking (DPM) e.g. surgical instruments.

Appendix A – Julian Calendar

Table A1

DAY OF MONTH	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	001	032	060	091	121	152	182	213	244	274	305	335
2	002	033	061	092	122	153	183	214	245	275	306	336
3	003	034	062	093	123	154	184	215	246	276	307	337
4	004	035	063	094	124	155	185	216	247	277	308	338
5	005	036	064	095	125	156	186	217	248	278	309	339
6	006	037	065	096	126	157	187	218	249	279	310	340
7	007	038	066	097	127	158	188	219	250	280	311	341
8	008	039	067	098	128	159	189	220	251	281	312	342
9	009	040	068	099	129	160	190	221	252	282	313	343
10	010	041	069	100	130	161	191	222	253	283	314	344
11	011	042	070	101	131	162	192	223	254	284	315	345
12	012	043	071	102	132	163	193	224	255	285	316	346
13	013	044	072	103	133	164	194	225	256	286	317	347
14	014	045	073	104	134	165	195	226	257	287	318	348
15	015	046	074	105	135	166	196	227	258	288	319	349
16	016	047	075	106	136	167	197	228	259	289	320	350
17	017	048	076	107	137	168	198	229	260	290	321	351
18	018	049	077	108	138	169	199	230	261	291	322	352
19	019	050	078	109	139	170	200	231	262	292	323	353
20	020	051	079	110	140	171	201	232	263	293	324	354
21	021	052	080	111	141	172	202	233	264	294	325	355
22	022	053	081	112	142	173	203	234	265	295	326	356
23	023	054	082	113	143	174	204	235	266	296	327	357
24	024	055	083	114	144	175	205	236	267	297	328	358
25	025	056	084	115	145	176	206	237	268	298	329	359
26	026	057	085	116	146	177	207	238	269	299	330	360
27	027	058	086	117	147	178	208	239	270	300	331	361
28	028	059	087	118	148	179	209	240	271	301	332	362
29	029	*	088	119	149	180	210	241	272	302	333	363
30	030		089	120	150	181	211	242	273	303	334	364
31	031		090		151		212	243		304		365

The HIBC Supplier Labeling Standard Format for use of Julian dating includes the last two digits of the year followed by a three-digit day-of-the-year code. For example, November 7, 1994 is represented as “94311” (the 311th day of 1994).

*A leap year has 366 days with February having 29. Julian dating in leap years is the same through February 28 (059) with February 29 as 060. All dating from March 1 through December 31 is incremented by one during leap years.

Appendix B – Check Character Calculations

B.1.0 Check Character Calculations

Be sure to use the Modulo 43 calculation when using the HIBC LIC data structures, whether Code 39 or Code 128 is used.

B.2.0 HIBC LIC Check Character Modulo 43 Generator

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Supplier Labeling Data Structure: + A 1 2 3 B J C 5 D 6 E 7 1
Sum of values: 41+10+1+2+3+11+19+12+5+13+6+14+7+1 = 145

Divide 145 by 43. The quotient is 3 with a remainder of 16. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 16, or "G". The complete Supplier Labeling Data Structure, including the Check Character, would therefore be:

+ A 1 2 3 B J C 5 D 6 E 7 1 G

Table of numerical value assignments for computing the HIBC LIC data format Check Character

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

B.2.1 Space Character Caution

The HIBC-LIC Check/Link character is **never** part of the **data message.** As such it should not normally be stored in a database or transmitted via EDI. It should be stripped away after the check and link functions have been executed. One of the possible values of the Check/Link Character is a space character (value 38). Although not recommended, if the link character must be stored or transmitted, the space character should be stored or transmitted explicitly as ASCII decimal 32 (ASCII Hex '20'). Note that some legacy systems and or software are unable to receive and or interpret trailing spaces as part of a data message.

Appendix C – Printing and Scanning Considerations

C.1 Printing Plates

Often, source printing requires the generation of a printing plate. Care should be given to produce the printing plate with smaller bars to compensate for ink spread. When “bar width reduction” or “X-dimension width reduction” is implemented, be sure that the spaces are enlarged by the same amount that the bars are reduced. The print quality requirement must be met on the final printed symbol. The printing plate can be fabricated using any method or accuracy as long as the final printed symbol meets the above specification.

C.2 Scanning Considerations

Scanners have different capabilities, be sure to match your scanner with your proposed symbol.

C.3 Example Symbols - Primary Data Structure

Example Data Structure:

+H123ABC01234567890D

Aztec Code

0.19" wide, 0.19" high
15 mil cell size, 19 x 19 matrix

Figure C1 Aztec Code

Data Matrix ECC200

0.18" wide, 0.18" high
15 mil cell size, 18 X 18 matrix

Figure C2 Data Matrix ECC200

QR Code

0.21" wide, 0.21" high
15 mil cell size, 21 X 21 matrix

Figure C5 QR Code 2005

Appendix D – Reference Definitions

For the purposes of printing the HIBC Supplier Labeling Symbol, the following informative definitions are included for convenience.

D.1 ISO/IEC 29158, Information technology – Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline
ISO Document detailing best practice methods to obtain and regulate quality of Direct Part Mark techniques.

D.2 Aztec Code
Aztec Code is a two-dimensional matrix style bar code symbology. Refer to ISO/IEC 24778.

D.3 Bars
The black or darker areas of the bar code symbol.

D.4 Code 128
A bar code pattern for alphanumeric data ideally suited to represent long strings of numeric digits with very high reading security. See ISO/IEC 15417.

D.5 Code 39
A bar code pattern for alphanumeric data ideally suited to printing processes that print one character at a time. When used with the symbology Check Character, Code 39 provides very high reading security. See ISO/IEC 16388.

D.6 Data Matrix
Data Matrix code is a two-dimensional matrix style bar code symbology that may be arranged in either a square or rectangular pattern. Refer to ISO/IEC 16022.

D.7 EHIBCC
EHIBCC (European Health Industry Business Communications Council) is an organization established in Brussels, Belgium for administration of the Health Industry Bar Code (HIBC) Supplier Labeling Standard. It is located at Jozef Israelaan 3, 2596 AM The Hague, The Netherlands. The telephone number for EHIBCC is +31-70-3244754 and the Fax number is +31-70-324-2522. For EHIBCC Technical Support, call +49-3445 781140. Web site: www.ehibcc.com

D.8 HDMA (formerly NWDA)
HDMA (Healthcare Distribution Management Association), formerly NWDA, provides guidance on the bar coding of pharmaceutical products. For information contact: HDMA, 901 North Glebe Road, Suite 1000, Arlington, VA 22203.
The telephone number is 703-787-0000. Fax: 703-787-6930. Web site: http://www.healthcaredistribution.org/

D.9 HIBC
Health Industry Bar Code.

D.10 HIBCC
HIBCC (Health Industry Business Communications Council) is the organization responsible for the development and maintenance of standards and services for use in the health care industry. HIBCC standards and information on its services, including the HIN System, the UPN Repository and other ecommerce applications are available from HIBCC at: 2525 E Arizona Biltmore Circle, Suite 127, Phoenix, Arizona 85016 or through one of the international offices. The telephone number for HIBCC is 602-381-1091. Fax: 602-381-1093. Email: info@hibcc.org Web site: http://www.hibcc.org.

D.11 HIDA
HIDA (The Health Industry Distributors Association) is an organization that develops and maintains guidelines for medical/surgical products in distribution and patient care. HIDA information is available from The Health Industry Distributors Association, 310 Montgomery St, Alexandria, Virginia 22314. The telephone number is 703-549-4432. Fax 703-549-6495. Web Site: http://www.hida.org.

D.12 ISO Linear Bar Code Print Quality Guideline
ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols should be used for determining print quality and monitoring the printing process

for linear symbols.

D.13 NDC
NDC (National Drug Code) is a 10-digit number administered by the FDA, typically for medication. For more information go to http://www.fda.gov/cder/ndc/database/default.htm

D.14 NHRIC
NHRIC (National Health Related Item Code) is a 10-digit number administered by the FDA. For more information go to http://www.fda.gov/cdrh/nhric/nhric.html

D.15 Quiet Zone
An area free of printing, preceding and following all standard bar code symbols, that is required for the decoding process. The quiet zones for Code 128 and Code 39 are at least ten times the X-dimension in size.

D.16 QR Code 2005
A **QR Code 2005** is a two-dimensional matrix style bar code symbology. Refer to ISO/IEC 18004.

D.17 Scannability
A general term describing the property of a bar code symbol whereby an attempt to use bar code reading hardware is successful. Symbols that meet ISO/IEC 15415 and ISO/IEC 15416 with a print quality level of C/06/660 generally will be scannable with a broad range of hand held bar code reading hardware.

D.18 Spaces
The white or lighter areas of the bar code symbol including the quiet zones.

D.19 Symbology
A set of rules for encoding information in a bar code symbol.

D.20 Two Dimensional Symbol Print Quality Guideline
ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols should be used for determining print quality and monitoring the printing process for 2D symbols.

D.21 Unit-of-Use
A packaging level containing the quantity of the item that is to be administered to a patient in a health care provider facility.

D.22 X-Dimension
The intended width of the narrow bar and narrow space in a bar code symbol.

Appendix E – HIBC Secondary Data Fields

E1.0 HIBC LIC Secondary Data Field

Appendix E describes the Secondary Data Formats with some examples. See Appendix F for a complete listing of Secondary Data Format options.

E1.1 Quantity/Date Fields

These examples are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is "G". Check characters have been calculated for these examples.

Quantity is either a two or five digit field describing the number of units-of-use included in the package identified by the bar code label. The options available for the Quantity and Date Fields are specified by the Quantity/Date/Lot/Serial Number Identifier "R" (see Section 2.2.1) and the first digit of the Quantity and the Date Fields. If the character following the leading "+" is numeric, then the Quantity/Date Identifier Field is null, the Quantity Field is also null and the digit is the first digit in the Julian Date (See Annex F).

For example:

+ 0 4 3 6 6 G X *Date is 12/31/04. The quantity field is null. The lot/batch/serial field is null.*

If the character following the leading "+" is a "$" but the next character is alphanumeric, then both the Quantity and Date Fields are null, and the character following the "$" is the first character in the Lot/Batch Number.

For example:

+ $ A 1 2 3 4 G U *Lot # is A1234*

If there is a two character lot number flag "$$", or a three character serial number flag "$$+", following the leading "+", then the first digit following will specify the Quantity and Date Field formats:

The digits 0 through 7 indicate that the Quantity Field is null and specify the Date Format:

- 0, 1 First digit of month in MMYY (month/year) Date format
- 2 MMDDYY (month/day/year) Date follows
- 3 YYMMDD (year/month/day) Date follows
- 4 YYMMDDHH (year/month/day/hour G.M.T.) Date follows
- 5 YYJJJ (year/Julian day) Date follows
- 6 YYJJJHH (year/Julian day/hour G.M.T.) Date follows
- 7 Date Field is null, Lot Field follows

The digits 8 and 9 specify the Quantity Field format. The first digit following the Quantity Field should be 0 through 7 to define the Date Field format as defined above.

- 8 Two digit Quantity Field follows
- 9 Five digit Quantity Field follows

For example:

+ $ $ 0 9 0 5 A 1 2 3 4 G /	*Date is 9/05 and Lot # is A1234,calculated Check Character is / .*
+ $ $ 8 7 2 4 0 4 1 2 1 5 2 3 G 2	*Quantity is 72 and Date is 12/15/04 23:00 G.M.T., calculated Check Character is 2.*
+ $ $ 9 0 1 4 4 0 7 A 1 2 3 4 G 8	*Quantity is 1440 and Lot # is A1234, calculated Check Character is 8.*

If the Secondary Code specifies only the Quantity, both the Date Field and the Lot/Batch/Serial Number Field should be null, not filled with zeroes, spaces or any other redundant characters, for example:

+ $ $ 8 4 8 G Q *Quantity is 48, calculated Check Character is Q.*

E1.2 Lot/Batch and or Serial Number Field

The Lot/Batch or Serial Number field can be alphanumeric and vary in length up to a maximum of 18 characters. If the field is not required (because neither Lot/Batch nor Serial Number is desired), the field should be null. The string header +$$ is used for Lot/Batch cases, with the new +$$+ being used exclusively for Serial Number implementations. While these will not become invalid, all new implementations should conform to this standard, and existing implementations brought in line with this standard as soon as feasible.

E1.3 Link Character

The Link Character is intended to link the Primary and Secondary Code Data Structures when encoded in separate linear symbols. The Link Character for the Secondary Data Structure is the last character from the Primary Data String in the Primary Symbol (Check Character).

Appendix F – Data Formats for HIBC Secondary Bar Codes

The following tables show the correct data formats for HIBC secondary bar codes. If a column is left blank, then that information is not used. The following field descriptions are used:

MM	2 digit expire date month indicator (fixed length of 2 numeric digits)
YY	2 digit expire date year indicator (fixed length of 2 numeric digits)
DD	2 digit expire date day indicator (fixed length of 2 numeric digits)
HH	2 digit expire date hour indicator (fixed length of 2, G.M.T. format)
JJJ	3 digit expire date Julian Day indicator (fixed length of 3 numeric digits)
LOT	up to 18-digit alpha/numeric lot/batch number
S/N	up to 18-digit alpha/numeric serial number
L	Link Character
C	Modulo 43 Check Character
QQ	2 digit quantity (fixed length of 2 numeric digits)
QQQQQ	5 digit quantity (fixed length of 5 numeric digits)

The following example data is always used in table F1:

Lot Number	3C001
Serial Number	0001
Link Character	L (Check Character from Primary Symbol)
Check Character	C (1 character Modulo 43 Check Character)
Expire	Date September 28, 2005 at 10 PM
2 digit Qty	24
5 digit Qty	00100

The following are the secondary data formats. As stated before, when encoding in separate linear symbols, the link character 'L' is the last character from the primary data string. If the primary message were +A123BJC5D6E71G as in example 4.3.1, the link character 'L' would have a value of 'G'. The Check Character 'C' has not been calculated in these examples.

Table F1

HIBCC Qty Flag	Qty Format Char	Qty Format	Exp Date Flag	Exp Date Format	Lot/Batch Field	Serial Number Field	Link Char	Mod 43 Ck Char	Example Data
+				YYJJJ	Note 1		L	C	+05271LC
+$					LOT		L	C	+$3C001LC
+$$				MMYY	LOT		L	C	+$$09053C001LC
+$$			2	MMDDYY	LOT		L	C	+$$20928053C001LC
+$$			3	YYMMDD	LOT		L	C	+$$30509283C001LC
+$$			4	YYMMDDHH	LOT		L	C	+$$4050928223C001LC
+$$			5	YYJJJ	LOT		L	C	+$$5052713C001LC
+$$			6	YYJJJHH	LOT		L	C	+$$605271223C001LC
+$$			7		LOT		L	C	+$$73C001LC
+$$	8	QQ		MMYY	LOT		L	C	+$$82409053C001LC
+$$	8	QQ	2	MMDDYY	LOT		L	C	+$$82420928053C001LC
+$$	8	QQ	3	YYMMDD	LOT		L	C	+$$82430509283C001LC
+$$	8	QQ	4	YYMMDDHH	LOT		L	C	+$$8244050928223C001LC
+$$	8	QQ	5	YYJJJ	LOT		L	C	+$$8245052713C001LC
+$$	8	QQ	6	YYJJJHH	LOT		L	C	+$$824605271223C001LC
+$$	8	QQ	7		LOT		L	C	+$$82473C001LC
+$$	8	QQ					L	C	+$$824LC
+$$	9	QQQQQ		MMYY	LOT		L	C	+$$90010009053C001LC
+$$	9	QQQQQ	2	MMDDYY	LOT		L	C	+$$90010020928053C001LC
+$$	9	QQQQQ	3	YYMMDD	LOT		L	C	+$$90010030509283C001LC
+$$	9	QQQQQ	4	YYMMDDHH	LOT		L	C	+$$9001004050928223C001LC
+$$	9	QQQQQ	5	YYJJJ	LOT		L	C	+$$9001005052713C001LC
+$$	9	QQQQQ	6	YYJJJHH	LOT		L	C	+$$900100605271223C001LC
+$$	9	QQQQQ	7		LOT		L	C	+$$90010073C001LC
+$$	9	QQQQQ					L	C	+$$900100LC
+$+						S/N	L	C	+$+0001LC
+$$+				MMYY		S/N	L	C	+$$+09050001LC
+$$+			2	MMDDYY		S/N	L	C	+$$+20928050001LC
+$$+			3	YYMMDD		S/N	L	C	+$$+30509280001LC

+$$+			4	YYMMDDHH		S/N	L	C	+$$+4050928200001LC
+$$+			5	YYJJJ		S/N	L	C	+$$+5052710001LC
+$$+			6	YYJJJHH		S/N	L	C	+$$+605271200001LC
+$$+			7			S/N	L	C	+$$+70001LC

Note 1: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5".

Note 2: Secondary Supplemental Data can be included in the data string by the following the rules defined in Section 2.3.

Appendix G - Unique Transport Unit ID Label

G1.0 Unique Transport Unit Identifier

Shipping containers (Unit Loads and Transport Packages) may be identified by a symbol that carries the Unique Transport Unit Identifier.

G1.1 Format Type

The Unique Transport Unit Identifier shall be the unique transport unit identifier using the ANSI MH10.8.2 Data Identifier "J":

G1.2 Scope

HIBC-LIC labeling may use ANS MH10.8.2 Data Identifier "J".

G2.0 Data Structure

The data structure using the ANSI Data Identifier "J" is as follows:

- JLHH123Z987654321, where
- J = ANS MH10.8.2 Data Identifier "J" – Unique Transport Unit Identifier.
- LH = Identifier for the Registration Authority – HIBCC/EHIBCC.
- H123 = HIBCC / EHIBCC Labeler Identification Code.
- 987654321 = Shipper's assigned number for the transport unit. (maximum 13 alphanumeric characters).

G3.0 Symbologies

The Unique Transport Unit Identifier may be represented using Code 128 or Code 39.

G4.0 Unique Transport Unit ID Label Example

Figure G1. Unique Transport Unit ID Label Example

For more information about transport package labeling, consult ANSI MH10.8.1, "For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

For more information about ANSI Data Identifiers, consult ANSI MH10.8.2, "ANSI Data Identifier Standard", available from ANSI (American National Standards Institute) in New York, telephone (212) 642-4900.

Appendix H – Backward Compatibility

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced and were acceptable until April 12, 1997. Among these are the alternate data format identified by "++", the use of stacked symbologies Code 16K and Code 49, and the unit-of-measure convention in the HIBC LIC Primary Symbol. Information about the previous version of this standard is available from HIBCC.

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced and are acceptable until April 12, 2014. Among these is the use of MicroPDF417 bar code symbology.

The recommended human-readable format for the HIBC LIC Primary and Secondary Symbol, always enclosing the human-readable data with the "*" regardless of symbology, should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

Appendix I – Bibliography

ISO/IEC 15459-1 Information technology -- Unique identifiers -- Part 1: Unique identifiers for transport units

ISO/IEC 15459-3 Information technology -- Unique identifiers -- Part 3: Common rules for unique identifiers

ISO/IEC 15459-4_Information technology -- Unique identifiers -- Part 4: Individual items

ISO/IEC 15459-6 Information technology -- Unique identifiers -- Part 6: Unique identifier for product groupings

ANS MH10.8.1, For Material Handling - Unit Loads and Transport Packages – Linear bar code and two-dimensional symbols used in shipping, receiving, and transport applications

ANS MH10.8.2-2006 American National Standard – Data Identifier and Application Identifier Standard

HDMA Numerical and Automatic Identification of Drug Products, Healthcare Distribution Management Association, 901 North Glebe Road, Suite 1000, Arlington, VA 22203, Phone: 703-787-0000

HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL (HIBCC)

CONFLICT OF INTEREST POLICY
AND
STATEMENT OF ACCEPTANCE

A. All officials (board members, officers, committee members) of the Health Industry Business Communications Council (HIBCC) shall scrupulously avoid conflicts – potential or real – between their own personal interests and those of HIBCC.

B. All officials of HIBCC have a fiduciary relationship with and owe a duty of loyalty to HIBCC. The fiduciary and loyalty obligations of officials require them to act on behalf of and for the benefit of HIBCC in all matters connected with or involving the interests of HIBCC. Therefore, it will be a conflict of interest and breach of the fiduciary and loyalty obligations for an official to:

- Actively solicit for or encourage a competitive venture;
- Fail or refuse to maintain and protect HIBCC's confidential, proprietary and/or trade secret information;
- Fail or refuse to assist, promote, encourage and, through the cooperative efforts of the officials, develop and advance the business and economic welfare of HIBCC.

C. Officials of HIBCC should not be financially interested or involved in any contract made by them in their official capacity or by the Board of Directors. Nor should said officials make sales to or purchases from this corporation or receive any compensation or fees for services to this corporation without the prior approval of the Board of Directors. Officials must disclose any direct financial interest or involvement in or with any matter coming before the board or committee.

D. Any official having a duality of interest or conflict of interest on any matter, (1) should make a full disclosure to the board, (2) should not vote or use personal influence on the matter, and (3) should be absent during the review and vote on the decisions in question. The minutes of the meeting should reflect that a disclosure was made, the abstention from voting, the absence

from the room during the review and vote. The foregoing requirements should not be construed as preventing the official from providing the board or committee with any and all relevant information known by the person having a conflict. When there is a doubt as to whether a conflict of interest exists, the matter shall be resolved by a vote of the Board of Directors or a committee, as the case may be, and the board member shall recuse him/herself from participating in the voting process.

E. Each official of HIBCC shall be given a copy of this conflict of interest policy and shall be required to disclose in writing any direct or indirect benefits each year, by no later than the close of HIBCC's fiscal year. This conflict of interest policy shall be reviewed periodically for the information and guidance, directors, officers and staff, and any new directors, officers, or staff shall be advised of the provisions of this policy upon undertaking the duties of such office.

_____

I acknowledge receipt and have read the above Conflict of Interest Policy and I agree to abide by its provisions during my tenure as an official of HIBCC.

Signature: _____

Printed Name: _____

Date: _____

Health Industry Business Communications Council

MEETING GUIDELINES FOR ANTITRUST POLICY

The HIBCC policy for Technical/Advisory Committee meetings prohibits any discussions, which constitute or imply an agreement or understanding concerning:

- Prices, discounts, or terms or conditions of sale
- Profits, or profit margins or cost data
- Market shares, sales territories or markets
- Allocation of customers or territories
- Selection, rejection or termination of customers or suppliers
- Restricting the territory or markets in which a company may resell products
- Restricting the customers to whom a company may sell

or any matter which is inconsistent with the proposition that each member company of the HIBCC Technical/Advisory Committees must exercise its independent business judgement in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HIBCC Technical/Advisory Committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items; there shall be no substantive discussions of HIBCC Technical/Advisory Committee matters other than at official meetings; and minutes shall be distributed to attendees promptly following adjournment of each meeting.

Health Industry Business Communications Council
STANDARD OPERATIONAL PROCEDURES
2013

1.0 TITLE

The name of the organization is the Health Industry Business Communications Council (HIBCC).

1.1 SCOPE

The primary function of HIBCC is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners.

1.2 RESPONSIBILITIES

HIBCC shall be responsible for developing proposed American National Standards (ANS) through the work of broad-based technical committees. The Auto-ID Technical Committee (AITC), and any subgroups created in accordance with these standard operating procedures, shall be responsible for developing, revising, re-affirming ANS and withdrawing ANS. Any substantive changes to ANS shall be referred to the AITC (the designated consensus body) for final approval (as indicated on the BSR-9). The HIBCC Board will provide oversight as designated herein, and will authorize by majority vote the submission to ANSI of the ANS. The HIBCC Board Chair shall serve as a voting member of the Committee. The HIBCC Board shall also have the right to approve the formation of additional technical committees as it deems necessary. HIBCC will maintain the standards in accordance with ANSI requirements and ensure that all requests for interpretation of the standard(s) are addressed according to the Interpretation Policy. In addition, all ANSI requirements for due process, criteria for accreditation and consensus will be met. HIBCC will ensure that the Standard(s) are periodically reviewed and continuously maintained. HIBCC will complete action (or request an extension of time) to revise, reaffirm or withdraw an ANS by the fifth year after the initial approval of the document as an ANS.

The HIBCC administrative office/secretariat shall organize technical committees, apply for committee accreditation by ANSI and maintain accreditation in accordance with ANSI requirements, including submission of the committee roster. In addition, HIBCC shall maintain a roster of the Committee and a list of the standards for which it is responsible. HIBCC shall provide a secretary to provide administrative work including secretarial services; meeting notices and arrangements; preparation and distribution of meeting agendas, minutes, ballots and draft standards; and maintenance of adequate records for each technical committee.

HIBCC shall submit candidate standards approved by the Committees and the HIBCC Board, with supporting documentation for ANSI review and approval as American National Standards and publish or arrange with ANSI for publication of its standards, revisions and addenda.

Any additional administrative functions as required by these procedures will be the responsibility of the HIBCC administrative office. These Standard Operating Procedures will be maintained by the HIBCC office and are subject to approval by a majority vote of the HIBCC Board. They will apply to the AITC, subgroups created by the AITC, as well as any other committees designated by the HIBCC Board.

2.0 OFFICERS

The HIBCC Chairman upon the approval of the HIBCC Board will appoint a chair and have the option of also appointing a co-chair for each Committee from the individual members of the Committee. Each will serve for one year and until a successor is selected and ready to serve. The co-chair shall carry out the chair's duties if the chair is temporarily unable to do so. Alternatively, a Committee secretary appointed by the HIBCC administrative office shall carry out the duties of the chair in the event of the absence of both the chair and a co-chair.

2.1 COMMITTEE PARTICIPATION

A request for representation on a Technical Committee shall be addressed to HIBCC and shall indicate the applicant's direct and material interest in the Committee's work, qualifications and willingness to participate actively, and, if the applicant is an organization, company or government agency, shall identify a principal (and an alternate, if desired) representative. All requests for Committee representation are subject to approval by the HIBCC Board and the Committee itself. Interested parties must attend two consecutive meetings as guests, in order to be considered for membership.

A modest annual registration fee is charged for each representative who attends Technical Committee meetings. Registration fees will be determined by the HIBCC Board and administered by the HIBCC Executive Office. It is not intended that the fees create undue financial barriers to participation. A request for a fee waiver may be made in writing to the HIBCC Executive office and will be considered based on individual circumstances.

2.2 RECOMMENDATION

In recommending appropriate action on applications for Committee representations, the HIBCC Board and Committee shall consider the following:

- Need for active participation by each interest;
- Potential for dominance by a single interest category;
- Extent of interest expressed by the applicant and the applicant's willingness to participate actively;
- The representative identified by the applicant organization, company or government agency.

The secretariat and/or HIBCC Board may consider reasonable limits on committee size.

2.3 DIVERSE INTERESTS

If distinct divisions of an organization can demonstrate independent interests and authority to make independent decisions with regard to the activity of the Committee, each may apply for Committee representation. If an interest is already represented on a Technical Committee, the secretariat may recommend that an applicant seek representation through the existing representative.

2.4 REVIEW OF COMMITTEE MEMBERSHIP

HIBCC shall review committee membership lists annually. Committee members are expected to fulfill obligations of active participation. When members are found in habitual default of these obligations, HIBCC shall direct the matter to the Committee chair and co-chair and/or the HIBCC Board for appropriate action, which may include termination of membership on the Committee.

2.5 OBSERVERS AND INDIVIDUAL EXPERTS

Individuals and organizations, having an interest in committee work may request listing as committee observers and will be subject to approval by the HIBCC Board. The Committee may also select individual experts to assist with Committee activities and deliberations. Individual experts shall serve for a renewable term of one year and shall be subject to approval by vote of the HIBCC Board. Observers and individual experts shall be advised of the Committee activities, may attend meetings, and may submit comments for consideration, but shall have *no* vote.

2.6 INTEREST CATEGORIES

All appropriate interests that might be directly and materially affected by the standards activity of HIBCC shall have the opportunity for fair and equitable committee participation without dominance by any single interest.

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

The standards development process should also have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

Each principal/alternate representative shall propose its own interest category as appropriate and in accordance with the Committee's established categories. Interest categories may include - user, producer and general interest as follows:

Healthcare Provider/User: Individual/Representative of healthcare facility or Organization using Auto-ID Technology.

Producer: Individual/Representative of Company or Organization manufacturing, distributing, producing or selling Auto-ID Technology.

General Interest: Individual/Representative of Company or Organization with a general interest in Auto-ID Technology and/or the Committee's work.

Interest categories shall be established or revised by a vote of the Committee upon recommendation by the HIBCC Board. The rationale for the selection of categories shall be included in the committee ballot and submitted to ANSI as part of the accreditation requirements.

2.7 MEMBERSHIP ROSTER

HIBCC shall maintain current Committee rosters and shall distribute them to the Committee representatives at least annually and otherwise on request. If changes are made to the roster, HIBCC shall redistribute it to all members.

The roster shall include the following:

- Title of the Committee and its designation;
- Scope of the Committee;
- Name of organization, secretary and addresses;
- Chair and co-chair of the Committee;
- Name, address and business affiliation of individual Committee member(s);
- Classification of each member;
- Tally of classifications: total of voting members and subtotals for each interest category;
- Title, name of chair and names and addresses of all members (including chair) of sub-groups if applicable.

2.8 TERMINATION OF MEMBERSHIP

Voting representation on the Committee shall be terminated upon failure to:

1) attend two out of three successive meetings, in which case the representation shall be terminated if not represented at the next meeting; or
2) respond to 80% of the total letter ballots (non-accelerated) closing during the current calendar quarter, in which case the representation shall be terminated if the member fails to respond to at least to the subsequent letter ballot; or
3) fulfill obligations of active participation per section 2.4 (i.e. habitual non-responsiveness to secretariat or Committee Chair, failure to complete assigned committee tasks in a timely manner, etc); or
4) pay all applicable committee representation registration, unless a fee waiver has been requested and granted.

The principal and all alternate representative(s) shall be notified in writing upon failure of the organization to meet any of the above conditions.

An organization and/or individual that has had their representation terminated may re-establish representation in accordance with 2.1 and 2.2. Under extenuating circumstance, the Committee or the HIBCC Board may vote to continue the representation despite failure of the member to comply with the representation criteria above.

2.9 RESIGNATION OF MEMBERSHIP

Resignation of membership in the Committee or any of its subgroups should be made in writing to HIBCC who will forward a copy to the appropriate Chair.

3.0 SUBGROUPS CREATED BY THE COMMITTEE

When one or more subgroups of a Technical Committee are formed, their formation (and later disbandment) requires approval by a majority vote of the Committee and the secretariat. The scope and duties delegated to the subgroup shall be outlined and approved at the time it is formed. Subsequent changes in scope or duties shall require additional approval. The charge to the subgroup shall clearly state in what way the subgroup is responsible for assisting the Committee (e.g. drafting all or a portion of a standard, drafting responses to comments, drafting positions on international standards, voting on approval of ANS revisions or re-affirmations, or other purely advisory functions.)

3.1 CHAIRPERSON AND MEMBERS OF SUBGROUPS

The chair and members of a subgroup shall be appointed by the chair of the Committee and confirmed by the Committee. The scope, duties, and membership of all subgroups shall be reviewed by the Committee annually. The chairs and members of a subgroup need not be members of the Committee.

4.0 APPROVAL OF STANDARDS

Draft standards and any substantive change in the content of a standard or withdrawal of a standard proposed by a subgroup shall be referred to the Committee for approval.

4.1 MEETINGS

Technical committee meetings shall be held, as decided upon by the Committee, the chair, the secretariat or by petition of five or more members, to conduct business, such as making assignments, receiving reports of work, considering draft standards, resolving differences among subgroups, and considering views and objections from any source. Meetings of subgroups may be held as decided upon by the members or chair of the subgroup.

4.2 OPEN MEETINGS

Technical Committee meetings shall be open to all parties having a direct and material interest. At least four weeks' notice of regularly scheduled meetings shall be given by the secretariat in ANSI's *Standards Action*; or in other media designed to reach directly and materially affected interests; or in both. The notice shall describe the purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest. The secretariat may optionally maintain a permanent mailing list of other interests.

5.0 QUORUM

The presence of 51% of members of the Committee shall constitute a quorum for conducting business at a meeting. If a quorum is not present, actions may be taken subject to confirmation by letter ballot.

6.0 VOTE

Each Committee member shall vote one of the following positions:

- Affirmative;
- Affirmative, with comment;
- Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objections);
- Abstain, with reasons.

6.1 VOTE OF ALTERNATE

An alternate's vote is counted only if the principal representative fails to vote.

6.2 SINGLE VOTE

Generally no Committee representative shall have more than one vote. However, if two or more organizations appoint the same individual to represent them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing to the secretariat that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the Committee, excluding the vote of that individual.

6.3 VOTING PERIOD

The voting period for letter ballots shall end two weeks from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the chair's option, when warranted. A follow-up letter requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members whose votes have not been received within five calendar days of the ballot close.

6.4 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF COMMITTEE REPRESENTATIVES

The following actions require approval by a majority of the Committee representatives at a meeting or by letter ballot, excluding abstentions:

- Formation of a Committee subgroup, including its procedures, scope and duties;
- Disbandment of subgroups;
- Addition of new Committee members and designation of their interest categories.

The following actions, by Committee vote at a meeting, require approval by a majority of the members present:

- Approval of minutes;
- Authorization of a letter ballot (unless initiated per Section 6.7).

6.5 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF THE HIBCC BOARD

The following actions require a letter ballot or an equivalent formal recorded vote with approval by at least a majority of the HIBCC Board, excluding abstentions:

- Adoption of Committee procedures, interest categories, or revisions thereto;
- Approval annually of Committee roster;

- Approval of change of Committee scope;
- Approval of termination of the Committee.

6.6 ACTIONS REQUIRING OPPORTUNITY FOR CONSIDERATION BY ENTIRETY

The following actions require the opportunity to cast a letter ballot or an equivalent formal recorded vote by all voting committee members and Board of Directors. Consensus within the Committee is required for all such actions:

- Approval of a new standard or reaffirmation and/or withdrawal of an existing one;
- Approval of revision or addendum to part or all of a standard.

All members of the Committee will be given the opportunity to vote on ANS related actions, even if they cannot attend a meeting (e.g. via follow-up confirmation ballot or the equivalent). Consensus will be determined by the majority voting rule (see Clause 6.8).

6.7 AUTHORIZATION OF LETTER BALLOTS

A letter ballot may be authorized by any of the following:

- Majority vote of those present at a meeting;
- The Chair;
- The HIBCC Executive Committee;
- The secretariat;
- Petition of five or more members of the Committee.

6.8 DEFINITION OF CRITERIA FOR APPROVAL

- **Majority**
  For on-site, hand meeting votes, a majority is defined as approval by more than half of the members voting, excluding abstentions and provided that a quorum is present. For letter ballot votes, a majority is defined as approval by more than half of the qualified voting membership, excluding abstentions.

7.0 OTHER REVIEW

Proposals for new ANS or reaffirmation, revision or withdrawal of existing ANS shall be transmitted to ANSI for listing in the *Standards Action* for comment.

The secretariat shall determine whether listing of proposed standards actions shall be concurrent with the final committee letter ballot and whether announcement in other suitable media is appropriate.

Views and objections resulting from the above shall be handled in accordance with section 8.0. Any substantive change made in the ANS shall be re-listed in accordance with the following.

8.0 DISPOSITION OF VIEWS AND OBJECTIONS

When the balloting on ANS has been closed, the ballot tally will be forwarded to the chair of the Committee or, if appropriate, of the subgroup; the chair shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting.

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in Standards Action.

Any comments received in response to the filing of PINS (Project Initiation Notification System) with ANSI for new and revised standards shall be addressed in accordance with clause 2.5 of the most current edition of the ANSI Essential Requirements.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each such objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists. In addition, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved will be reported to the ANSI BSR. All substantive changes made to an ANS resulting from public comment or in an attempt to resolve a consensus body vote will be re-listed for public review.

HIBCC may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Each unresolved objection and attempt at resolution, and any substantive change made in a proposed ANS shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm, or change their vote within two weeks.

8.1 REPORT OF FINAL RESULT

The final results of the voting shall be reported, by interest categories, to the Committee.

9.0 SUBMITTAL OF STANDARD

Upon completion of the procedures for voting, disposition of views and objections, and appeals, the proposed standard shall be approved by the HIBCC Board and submitted to ANSI by the secretariat. The proposed ANS will be submitted to ANSI within one year of the close of the public review period, or two years, if an extension is requested in accordance with clause 4.2 of the ANSI Essential Requirements. If the secretariat does not submit the proposal to ANSI within a reasonable period of time, any member(s) of the Committee may make the submittal.

9.1 INFORMATION SUBMITTED

With respect to submitting American National Standards to ANSI without BSR approval, HIBCC shall agree to provide ANSI the following:

1. title and designation of the proposed American National Standard;
2. indication of the type of action requested (that is, approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard);
3. a declaration that applicable procedures were followed;
4. a declaration that the proposed standard is within the scope of the previously registered standards activity;
5. a declaration that conflicts with another American National Standard have been addressed in accordance with these procedures;
6. a roster of the consensus body that indicates: the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
7. a declaration that all appeal actions related to the approval of the proposed standard have been completed;
8. a declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
9. identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

9.2 DISCONTINUANCE OF A STANDARDS PROJECT

An accredited standards developer may abandon the processing of a proposed new or revised American National Standard or portion thereof if it has followed its accredited procedures. A written justification for such an action shall be made available upon receipt of any written request received by the accredited standards developer within 60 days of the date of the final action.

Appeals of such actions shall be made to the HIBCC Board based on procedural noncompliance.

10.0 TERMINATION OF COMMITTEE

A proposal to terminate a Technical Committee may be made by a directly and materially affected interest to the HIBCC Board. Proposals to disband sub-committees should be directed to the primary

Committee under which they are governed. The proposal shall be submitted in writing and shall include at least the following:

- Reasons why the Committee (or sub-committee) shall be terminated;
- The name(s) of the organization(s) or committee(s) that will assume responsibility for maintenance of any existing ANS that are the responsibility of the Committee.

In the instance that a sub-committee has governance of an existing ANS, the ANS will revert back to the primary committee under which they were governed.

11.0 COMMUNICATIONS

Copies of correspondence involving issues or decisions (i.e. not routine matters) affecting other sub-committees shall be sent to all affected Committee chairs and the secretariat.

Inquiries relating to Committees should be directed to the secretariat. All replies to inquiries shall be made through the secretariat.

All inquiries requesting interpretation of approved ANS shall be responded to in accordance with HIBCC's interpretation policy. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.

12.0 APPEALS

Persons who have direct and materially affected interests and/or who have been or will be adversely affected by a standard within the Committee's jurisdiction shall have the right to appeal procedural actions or inactions of the Committee or the secretariat.

12.1 COMPLAINT

The appellant shall file a written complaint with the secretariat within thirty days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objections(s) including any adverse effects, the clause(s) of these procedures or the standard that are at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

12.2 RESPONSE

Within thirty days after receipt of the complaint, the Committee chair or secretariat shall respond in writing to the appellant, specifically addressing each allegation or fact in the complaint to the extent of the respondent's knowledge.

12.3 HEARING

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the secretariat shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten working days notice.

12.4 APPEALS PANEL

The appeals panel shall consist of three individuals plus one alternate who have been elected by the HIBCC Board. In the case that one of the individuals can not take part in the appeals process due to either the inability to attend or if one of the parties in question requests the person be replaced, the alternate shall be used. Panel members shall serve a term of one year. The panel shall consist of a balanced representation from the represented interest groups, and will exclude any persons currently serving within the consensus body.

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the committee and the secretariat took all actions in compliance with these procedures. Each party may introduce other pertinent arguments, and members of the appeals panel may address questions to individuals. *Robert's Rules of Order* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

12.5 DECISION

The appeals panel shall render its decision in writing within thirty days, stating findings of fact and conclusions, with reasons therefore, based on preponderance of the evidence. Consideration may be given to the following positions, among others, in formulating the decision:

- Finding for the appellant, remanding the action to the committee or the secretariat with a specific statement of the issues and facts in regard to which fair and equitable action was not taken;

- Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections;

- Finding that new, substantive evidence has been introduced, and remanding the entire action to the Committee or the secretariat for appropriate reconsideration.

13.0 PARLIAMENTARY PROCEDURES

On questions of parliamentary procedure not covered in these procedures, *Robert's Rules of Order* (latest edition) may be used to expedite due process.

ANNEX A: POLICIES

Interpretation Policy

Due to potential liability issues, HIBCC will not provide interpretations of its standards.
All written and oral requests for interpretation of approved HIBCC standards will be received by the HIBCC administrative office. These requests for interpretations will be processed as follows: A form letter shall be sent to the requester, informing the requester that no interpretations are provided and suggests that the requestor participate in HIBCC to revise the standard so it is clearer.

Note: " interpretations of its standards" means the clarification of any portion of the standard(s) that contains ambiguous wording. Explanations of technical specifications are not "interpretations of its standards".

Metric Policy

In general, HIBCC standards will adopt style rules that utilize units of measurement according to the International System of Units (SI), the modernized metric system.

When referencing technical specifications of system components that would potentially use HIBCC standards, the HIBCC standard(s) may adopt the same units of measurement that are used in those technical specifications.

Record Retention Policy

Records relating to any standards activity shall be retained to demonstrate compliance with all aspects of ANSI Essential Requirements and HIBCC's Standard Operating Procedures.

Records concerning new, revised, or reaffirmed American National Standards shall be retained by HIBCC for one complete standards cycle, or until the standard is revised.

Records concerning withdrawn standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

Patent Policy

The Health Industry Business Communications Council (HIBCC), does not hold and does not currently intend holding any essential patent claim(s). HIBCC will comply with the ANSI Patent Policy.

Commercial Terms & Conditions Policy

The Health Industry Business Communications Council (HIBCC) does not have its own Commercial Terms and Conditions Policy. HIBCC will comply with the ANSI Commercial Terms and Conditions Policy.

Health Industry Business
Communications Council

Agreement of Non-Disclosure of Confidential Information

This LETTER OF AGREEMENT will serve to confirm and set forth the terms of agreement between the Health Industry Business Communications Council (HIBCC) and **NAME** (herein referred to as "Primary Consultant"). In consideration of the mutual undertakings of HIBCC and the Primary Consultant, the parties agree as follows:

In the course of this Agreement, Primary Consultant acknowledges that he may have access to information that HIBCC considers confidential, proprietary and/or sensitive, the disclosure of which could result in substantial and irreparable damage to HIBCC.

Definition of Confidential Information:
Confidential information shall mean business or technical information including, but not limited to, product data, sales data, financial data, customer data, formula processes, techniques and methods or ideas that are not generally known or available. Confidential Information shall also include information of HIBCC Affiliates that HIBCC is under an obligation to maintain in confidence.

No Disclosure of Confidential Information:
Primary Consultant agrees that he will regard and preserve as confidential all Confidential Information of HIBCC and its Affiliates received by Primary Consultant in connection with this agreement. To preserve the confidentiality of such Confidential Information Primary Consultant will not, without first obtaining the written consent of HIBCC, disclose to any person, firm or enterprise, or use for his own benefit, any such Confidential Information.

Limits on Confidential Information:
Confidential Information shall not be considered confidential, proprietary or sensitive only to the extent that such information: (a) is already known to Primary Consultant at the time it is obtained from HIBCC; (b) is or becomes publicly known through no wrongful act of Primary Consultant; or (c) is rightfully received by Primary Consultant from a third party without an accompanying restriction of use or disclosure.

Confidentiality of Work Products:
All work products developed by Primary Consultant for HIBCC and its Affiliates, including but not limited to computer programs and applications and associated documentation, shall be the sole property of HIBCC and are subject to the terms of this Agreement as deemed appropriate by HIBCC.

Terms & Termination:
This Agreement shall remain in effect after termination of the work contract/employment.

This Non-Disclosure Agreement shall be interpreted in accordance with and governed by the laws of the State of Arizona.

In the event of breach or a threatened breach of terms and conditions of this Agreement, HIBCC shall be entitled to immediate injunctive relief to prevent the use or disclosure of Confidential Information, in addition to all other remedies available to it at law or equity.

Any suit or action arising out of a dispute under this Agreement shall be brought only in a court of competent jurisdiction, state or federal, sitting in Phoenix, Arizona. Both parties agree to accept venue in such county.

Accepted this 8th day of October, 2013.

HIBCC

By_____

Name: Robert A. Hankin

Title: President & CEO

Primary Consultant

By_____

Name:

Title: Consultant

Hawthorn, Anne T.

From: Kirk Kikirekov <kirk.kikirekov@hibcc-au.com.au>
Sent: Tuesday, December 10, 2013 1:27 PM
To: Fields, Erin; Hawthorn, Anne T.
Cc: Robert Hankin, HIBCC; sjpolan@hibcc.org
Subject: HIBCC Application - Issuing Agency

Importance: High

Dear Erin and Anne,

Further to our telephone call today, I can confirm that for the purpose of UDI, the following table defines the sole pathway for UDI. We will be issuing guidelines to our subscribers to advise them accordingly.

Regards

Kirk

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	+	DI	Alphanumeric	7-24	6-23
HIBCC	$	Lot Number Only	Alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	$$	Expiration Date followed by Lot Number	Exp Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed by Lot Number	Exp Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$4	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	$$5	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	$$6	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	alphanumeric	20	18

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	$$+7	Serial Number only (alternative option)	Alphanumeric	22	18
HIBCC	$$+	Expiration Date followed by Serial Number	Exp Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	$$+2	Expiration Date followed by Serial Number	Exp Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+3	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+4	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	$$+5	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	$$+6	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC		***Base UDI***	***alphanumeric***	***70-87***	***58-75***

Ex of Human Readable Barcode:
+H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ4567890123
45678/16D20130202C

87 is the maximum possible data string encoded in the barcode, including the identifying symbols and the separator "/". The identifying symbols are not included in the database field size.

The max possible data string is where expiry date is formatted as YYMMDDHH and the barcode includes a lot number and serial number and Manufacture date.

Ex of barcode: *+H728716422350J*
+$$121808LT25980JH

Kirk Kikirekov
President
HIBCC AU Incorporated
Tel: 02 9715 1647
Mob: 0400 228 117
www.hibcc-au.com.au

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