



STATEMENT OF COOPERATION

AMONG

THE UNITED STATES FOOD AND DRUG ADMINISTRATION



THE AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION



THE BRAZILIAN HEALTH SURVEILLANCE AGENCY



AND

THE CANADIAN HEALTH PRODUCTS AND FOOD BRANCH



**REGARDING COOPERATION IN THE MEDICAL DEVICE SINGLE AUDIT
PROGRAM**

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The United States Food and Drug Administration (FDA), the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), and the Canadian Health Products and Food Branch (HPFB) (collectively “the Participants”) seek to strengthen existing mutual cooperation in the scientific and regulatory area of medical devices through the development of the Medical Device Single Audit Program (MDSAP), as documented by this Statement of Cooperation (SOC).

The goal of the MDSAP is to provide for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers. The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the Participants.

The objectives of the MDSAP are to:

1. Operate a single audit program that provides confidence in program outcomes;

2. Enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry;
3. Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among Participants, while respecting the sovereignty of each country;
4. Promote, over the longer term, greater global alignment of regulatory approaches and technical requirements based on international standards and best practices;
5. Promote consistency, predictability and transparency of regulatory programs by standardizing oversight practices and procedures of Participants over third-party auditing organizations, and the practices and procedures of participating third-party auditing organizations; and
6. Leverage, where appropriate, existing conformity assessment structures.

The Participants, in accordance with their respective legal authorities, intend to develop a joint work plan as appropriate for the MDSAP. This work plan is intended to enable the pooling of technology, resources, and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry.

Each Participant to this SOC intends to fund its its participation in activities under this SOC. All such participation is subject to the availability of appropriated funds (where applicable), personnel, and other resources. Each Participant intends to maintain the confidentiality of the information shared under this program according to its own procedures and policies as permitted by its laws.

This SOC is not intended to create binding obligations under international or domestic law. Nothing in this SOC is intended to negatively affect the Participants' responsibilities or ability to carry out their regulatory responsibilities and programs in accordance with their respective laws and regulations.



This SOC may commence upon signature of all the Participants. A Participant may discontinue its participation in the development of the MDSAP upon sixty (60) calendar days' written notice to the other Participants.

Signed in Manaus, Brazil, on this 27th day of November 2012, in English, French and Portuguese languages, each version being equally valid.

For the Food and Drug Administration

UNITED STATES OF AMERICA:

Signature on File

Margaret A. Hamburg, M.D.

Commissioner of Food and Drugs

For the Therapeutic Goods Administration

AUSTRALIA:

Signature on File

Dr. John Skerritt

National Manager

For the Brazilian Health Surveillance Agency

BRAZIL:

Signature on File

Dirceu Barbano, MS.

Director Chairman

For the Health Products and Food Branch

CANADA:

Signature on File

Paul Glover

Assistant Deputy Minister