DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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To whom it may concern,

The Medical Device Single Audit Program (MDSAP) was established by a coalition of international medical device regulatory authorities including the Therapeutic Goods Administration (TGA) of Australia, Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) and the U.S. Food and Drug Administration.

The goal of the Medical Device Single Audit Program (MDSAP) is to allow a single regulatory audit of a medical device manufacturer's quality management system (QMS) to satisfy the needs of the participating regulatory jurisdictions.

The Medical Device Single Audit Program (MDSAP) enables medical device manufacturers to contract with an authorized third-party Auditing Organization to conduct a single audit of the medical device manufacturer that will satisfy the relevant regulatory requirements of the participating medical device regulatory authorities including the U.S. Food and Drug Administration.

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), the Quality System Regulation (21 CFR Part 820), and specific requirements of medical device regulatory authorities participating in the MDSAP program including the U.S. FDA's 21 CFR 803, 806, 807, and 821.

At the conclusion of an MDSAP audit, a standardized MDSAP Audit Report is generated. The standardized MDSAP Audit Report template was developed to assure the reporting requirements of all participating regulatory authorities (including the U.S. FDA) are effectively documented.

The U.S. Food and Drug Administration (FDA) recognizes MDSAP audit reports as a substitute for FDA Establishment Inspection Reports (EIRs).

[Signature on file]

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