ACCESS POINT
TECHNOLOGIES EP

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Declaration of Conformity

Manufacturer:
Name: Access Point Technologies EP, Inc.
Address: 12560 Fletcher Lane, Suite 300 Rogers, MN 55374 USA
Phone: 763-432-9004
Fax: 763-432-9305

EC Representative:
Name: Healthlink Europe B.V.
Address: DeTweeling 20-22 5215 MC 's-Hertogenbosch, The Netherlands
Phone: +31-13-547-9300
Fax: +31-13-547-9301

Device Name and Type:
Electrophysiology Catheters. It includes APT EP Map-iT™ Diagnostic Mapping Catheters and APT EP Map-iT™ Steerable Ablation Catheters. The model list is in Section 01 of this Design Dossier.

Classification and Conformity Route:
According to 93/42/EEC Annex IX, Rule 7, Mapping and Ablation Catheters are Class III devices. The Conformity Route is Annex II, including section 4.

GMDN Reference Number:
- 46355 - Cardiac mapping catheter, percutaneous, single use
- 61785 - Cardiac radio-frequency ablation system catheter

We hereby declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards, and it is also in conformance with transposition of the directive into the national law of the member states. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14JUN1993 concerning medical devices.

Harmonized Standards:
Harmonized Standards (published in the Official Journal of the European Union C289/29 (Publication of titles and references of harmonised standards under Union harmonisation legislation), dated 17.11.2017:

EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated STERILE". Requirements for terminally sterilized medical devices"
EN 1041:2008 Information supplied by the manufacturer of medical devices
EN ISO 10555-1: 2009 Sterile, single---use intravascular catheters --- Part 1: General requirements
EN ISO 10993-1:2009 Biocompatibility requirements biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)
EN ISO 10993-4:2009 Biological Evaluation of Medical Devices, Part 4: Selection of Test for Interactions with Blood
EN ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for in vitro Cytotoxicity
EN ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2009 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity
EN ISO 10993-12:2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials
EN ISO 11135:2007 Sterilization of healthcare products – Ethylene Oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11138-2:2009 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices. Part 1 -Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices. Part 2-Requirements for forming, sealing and assembly
EN ISO 11737-1:2015 Sterilization of medical devices: Microbiological methods- Part 1: Estimation of population of microorganisms on products
EN ISO 11737-2:2015 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes
*ISO 14698-1:2003 - Cleanrooms-Biocontamination Control-Part1-General principles and methods.
*ISO 14698-2:2003 - Cleanrooms-Biocontamination Control-Part 2-Evaluation and interpretation of biocontamination data.
EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2016 Medical Devices: symbols to be used with medical device labels, labelling and information to be supplied Part 1-General Requirements
IEC 60601-1:2012 (Base Standard) Medical electrical equipment. General requirements for basic safety and essential performance EN 60601-1 Ed.3 (2007) + Amendment 1 (2013)
IEC 60601-1:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN 62366:2008 Medical devices-Application of usability engineering to medical devices
*MEDDEV 2.7/1 revision 4, June 2016 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
*MEDDEV 2.12/1 rev.8 Guidelines on a medical devices vigilance system January 2013

*Not in the Official Journal of the European Union C289/29 (Publication of titles and references of harmonised standards under Union harmonisation legislation) dated 17.11.2017.

Notified Body:
SZUTEST Uygunluk Degerlendirme Kurulusu A.S.
Address: Szutest Plaza, Nata Yalu Cad/Cam Sokak No. 7 Umraniye /34774 Istanbul, Turkey
Phone: +90 216 469 4666
Fax: +90 216 469 4667
Identification Number: 2195

Certificate:
EC Certificate 2195-MED -1323801.

Certificate:
EC Design Examination Certificate 2195-MED-1323801-D0l.

REACH Declaration:
REACH (EC1907/2006) The Registration, Evaluation, Authorization, and Restriction of Chemicals APT EP Inc. does not intentionally add substances of very high concern (REACH SVHC) into the MAP-iT™ Electrophysiology Catheters. APT EP Inc. further certifies that its suppliers for the MAP-iT™ Electrophysiology Catheters do not intentionally add substances of very high concern (REACH SVHC) or the substances are less than the REACH threshold of 0.1%.

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RoHS Declaration:
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the "Restriction of Hazardous Substances in Electrical and Electronic Equipment (recast)" (RoHS2), and related amendments (RoHS3).

APT EP Inc. declares that its MAP-iT™ Electrophysiology Catheters have been examined with the respect to the above referenced EU directives, and to the best of our knowledge, do not contain the listed concentration of the list of substances. In preparing this statement, APT EP Inc. has reviewed information provided by our raw material suppliers, our own designs, and knowledge of our manufacturing processes.

1. Lead (Pb):< 1000 ppm
2. Mercury (Hg):< 100 ppm
3. Cadmium (Cd):< 100 ppm
4. Hexavalent Chromium: (Cr VI)< 1000 ppm
5. Polybrominated Biphenyls (PBB): < 1000 ppm
6. Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
7. Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
8. Benzyl butyl phthalate (BBP): < 1000 ppm
9. Dibutyl phthalate (DBP): < 1000 ppm
10. Diisobutyl phthalate (DIBP): < 1000 ppm

Latex Declaration:
APT EP Inc. does not introduce any natural rubber latex in the manufacturing process of its MAP-iT™ Electrophysiology Catheters. APT EP Inc. further certifies that its suppliers do not intentionally add natural rubber latex to the components of the MAP-iT™ Electrophysiology Catheters.

Product Covered:
All devices mentioned produced after 08/29/2013.

Signature: Charlotte Gasperlin Date: 3/17/20
Name/Position: Charlotte Gasperlin, Sr. Director of Regulatory and Quality