

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1323801

Manufacturer: Access Point Technologies EP, Inc.
12560 Fletcher Lane, Suite 300 Rogers, Minnesota 55374 USA

Product(s): (1) Map-iT™ Sterile Single Use Electrophysiology Catheters
(2) Map-iT™ Sterile Single Use Mapping and Ablation Catheter Extension Cables

Model(s): Product specifications are stated on the following page(s).

Reference Report No: MM0008-P008-R01, MM0008-P008-R02, MM0008-P008-R03

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2013-08-26
Revision No.: 03 Recertification
Revision Date: 2020-02-28



Rukiye BALKAN
Deputy General Manager

SZUTEST

Certificate Number: 2195-MED-1323801

Product Specifications:

Product Name	Model Name
Map-iT™ Sterile Single Use Electrophysiology Catheters	Fixed Curve Diagnostic Catheter
	Fixed Curve Diagnostic Catheter with 1.6mm Tip
	Fixed Curve Diagnostic Catheter with Guidewire Tip
	Steerable Diagnostic Catheter
	Steerable Ablation Catheter 4MM TC
	Steerable Ablation Catheter 4MM THR
	Steerable Ablation Catheter 8MM TC
	Steerable Ablation Catheter 8MM THR
	Steerable Bi-D Irrigated Tip Ablation Catheter 4MM TC
	Steerable Bi-D Irrigated Tip Ablation Catheter 4MM THR
	Steerable Bi-Directional Ablation Catheter 4MM TC
	Steerable Bi-Directional Ablation Catheter 4MM THR
	Steerable Bi-Directional Ablation Catheter 8MM TC
	Steerable Bi-Directional Ablation Catheter 8MM THR
	Steerable Irrigated Tip Ablation Catheter 3MM TC
	Steerable Irrigated Tip Ablation Catheter 4MM TC
	Steerable Irrigated Tip Ablation Catheter 4MM THR
Map-iT™ Sterile Single Use Diagnostic Mapping and Ablation Catheter Extension Cables	Mapping Catheter Extension Cable
	Steerable Ablation Catheter Extension Cable



SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

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EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-1323801-D01

Manufacturer: Access Point Technologies EP, Inc.
12560 Fletcher Lane, Suite 300 Rogers, Minnesota 55374 USA

Product(s): Map-IT™ Sterile Single Use Electrophysiology Catheters

Model(s): Product specifications are stated on the following page(s).

Reference Report No: MM0008-P008-R01, MM0008-P008-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-05-26.

Issue Date: 2013-08-26
Revision No.: 03 Recertification
Revision Date: 2020-02-28



Rukiye BALKAN
Deputy General Manager

Certificate Number: 2195-MED-1323801-D01

Product Specifications:

Product Name	Model Name
Map-iT™ Sterile Single Use Electrophysiology Catheters	Fixed Curve Diagnostic Catheter
	Fixed Curve Diagnostic Catheter with 1.6mm Tip
	Fixed Curve Diagnostic Catheter with Guidewire Tip
	Steerable Diagnostic Catheter
	Steerable Ablation Catheter 4MM TC
	Steerable Ablation Catheter 4MM THR
	Steerable Ablation Catheter 8MM TC
	Steerable Ablation Catheter 8MM THR
	Steerable Bi-D Irrigated Tip Ablation Catheter 4MM TC
	Steerable Bi-D Irrigated Tip Ablation Catheter 4MM THR
	Steerable Bi-Directional Ablation Catheter 4MM TC
	Steerable Bi-Directional Ablation Catheter 4MM THR
	Steerable Bi-Directional Ablation Catheter 8MM TC
	Steerable Bi-Directional Ablation Catheter 8MM THR
	Steerable Irrigated Tip Ablation Catheter 3MM TC
	Steerable Irrigated Tip Ablation Catheter 4MM TC
	Steerable Irrigated Tip Ablation Catheter 4MM THR

