Medtronic

MANUFACTURER'S DECLARATION OF CONFORMITY
FULL QUALITY ASSURANCE PROCEDURE

This declaration of conformity confirms that the product(s) mentioned meet the requirements of the Medical Device Directive 93/42/EEC and the transportation of these requirements in the legislation of the country we are selling. This is also a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device(s).

Manufacturer's Name: *Covidien llc*
Business Address: *15 Hampshire Street*
Mansfield, MA 02048
USA

Authorized EC Representative: *Covidien Ireland Ltd*
IDA Business & Technology Park,
Tullamore, Ireland

Medical Device(s): *Barrx™ 360 RFA Balloon Catheters (models 32041-xx)*
Barrx™ 60 RFA Focal Catheter (model 90-9300)
Barrx™ 90 RFA Focal Catheter (model 90-9100)
Barrx™ Ultra Long RFA Focal Catheter (model 90-9200)
Barrx™ Channel RFA Endoscopic Catheter (TTS-1100)
Barrx™ 360 Express RFA Balloon Catheter (64082)

Classification: *IIb*

GMDN Code and Term: *57972 Type P Radio-frequency ablation system*

Scope of Application:
Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each state, from the design of the device until its final inspection before being supplied.

Notified Body:
Presafe Denmark A/S
Tuborg Parkvej 8, 2900 Hellerup, Denmark
Identification No. 0543

Full Quality Management System Certificate:
- Presafe Denmark A/S: ISO 13485:2003; Scope: Design, manufacturing, service and distribution of RF Surgical Devices, Esophageal and Electrosurgical Catheters and related accessories for gastrological and esophageal ablation, Endoscopic Ultrasound Needle Aspiration System and sample collection devices.
  Reference: aur2a1505v40f798 (Valid Until: 2018-07-02).
- SAI Global Certificate of Registration: ISO 13485:2003 CMDCAS; Scope: Design, Manufacture, Service and Delivery of RF Generators and Esophageal Catheters and Endoscopic Ultrasound Needle Aspiration and Biopsy Systems
  Reference: CERT-0085815 (Valid Until: 2018-08-19).
- Presafe Denmark A/S: Annex II section 3.2-Full quality assurance system of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law excluding Annex II, section 4; Scope: Design, manufacture and final inspection of energy generators and ablation

catheters for esophageal and gastrological ablation in class IIb, related accessories in class IIa and debris removers in class I sterile. Design, manufacture and final inspection of Endoscopic Ultrasound Needle Aspiration and Biopsy Systems in class IIa and sample collection devices in class Is.
Reference: aur2a1706v120f798 (Valid Until: 2022-07-01).

Design Examination Certificate: *Not Applicable*

Standards Applied: *Refer to Essential Requirements Matrix for the list of applicable standards*

Authorized Signatory:

Saket Bhatt 03 July, 2017

Saket Bhatt, Date
Regulatory Affairs Manager