



EC Declaration of Conformity

Perseon Corporation
460 West 50 North, Suite 100, SLC, UT 84101, USA

Does hereby declare under our sole responsibility that the MicroThermX® Microwave Ablation System and accessories, which includes device catalog numbers referenced in the attached list, are Class IIb per Annex IX, Rule 9, meets the provisions and essential requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD), as amended by 2007/47/EC and with the relevant European Union harmonization legislation Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), as transposed in the national laws of the Member States.

In addition, MicroThermX® Microwave Ablation System accessories (Sterile) fall within Class IIa, according to rule 7 of Annex IX of the EC Directive.

The regulatory route demonstrating the conformity is based on the criteria of Annex II audited by DQS Medizinprodukte GmbH, Identification Number 0297, located at August-Schanz-Strabe 21, 60433 Frankfurt am Main, Germany, as an appointed Notified Body.

Certificate No.: 349980 MR2 Technical File No.: 15-17627

Effective: 19-Nov-15 thru 16-Jun-2016

Authorized Representative in the European Community: Emergo Group B.V.
Molenstraat 15
2513 BH, The Hague, The Netherlands
Tel: +31 (0)70 345 8570

19 NOVEMBER 2015

Rick Gaykowski
Corp. V.P., Regulatory, Quality, & Clinical Affairs

Date

On this 19th day of November, 2015, personally appeared before me Rick Gaykowski, whose identity is personally known to me, and who, being duly sworn, did say that Rick Gaykowski is the Corp. V.P., Regulatory, Quality, & Clinical Affairs, for Perseon Corporation, and that said document was signed by him in behalf of said corporation by authority of its bylaws.

Carol Freasier



This product complies with the following standards:

Medical Device Directive 93/42/EEC

EN ISO 13485:2012/AC:2012,
EN ISO 14971:2012,
EN 60601-1:2006/AC:2010,
EN 60601-1-2:2007/AC:2010,
EN 60601-1-6:2010,
EN 62304:2006/AC:2008,
EN 62366:2008,
EN 55011 Class A:2007 (CISPR 11:2009),
EN ISO 10993-1:2009/AC:2010,
EN ISO 10993-5:2009,
EN ISO 10993-7:2008/AC:2009,
EN ISO 10993-10:2009,
EN ISO 11135-1:2014,
EN ISO 11607-1:2009/A1:2014,
EN ISO 11607-2:2006,
EN 980:2008,
EN 1041:2008

Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ C 149 of 16/05/2014).

RoHS Directive 2011/65/EU

BS EN 50581:2012,
BS EN 62321:2009,
IEC/TR 62476:2010

Commission communication in the framework of the implementation of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ C 363 of 23/11/2012).

Other relevant international standards

ISO 13485:2003,
ISO 14971:2007,
IEC 60601-1:2005/A1:2012,
IEC 60601-1-2:2014,
IEC 60601-1-6:2010,
IEC 60601-2-6:2012,
ANSI/AAMI/IEC 62304:2006,
ANSI/AAMI/IEC 62366:2015,
ISO 10993-1:2009,
ISO 10993-5:2009,
ISO 10993-7:2008,
ISO 10993-10:2010,
ASTM D-4169:2014,
ANSI/AAMI/ISO 11135:2014,
AAMI TIR 28:2009,
ANSI/AAMI/ISO 11607-1:2006/A1:2006,
ANSI/AAMI/ISO 11607-2:2006/A1:2006,
ISO 15223-1:2012,
ISO 15223-2:2010

MicroThermX® Microwave Ablation System

Catalog Number	Product Name	Device Type	Class	Rule	GMDN
MTX-180E	MicroThermX® Microwave Ablation System	Generator and Wheeled Cart System	IIb	9	40783
MTX-180-T2-E	MicroThermX® Microwave Ablation System T2	Generator and Tabletop System	IIb	9	40783
SWST-1415	SynchroWave ST Antenna Kit, 15cm	Sterile Disposable Antenna Kit	IIb	9	40783
SWST-1420	SynchroWave ST Antenna Kit, 20cm	Sterile Disposable Antenna Kit	IIb	9	40783
SW-1415	SynchroWave LT Antenna Kit, 15cm	Sterile Disposable Antenna Kit	IIb	9	40783
SW-1420	SynchroWave LT Antenna Kit, 20cm	Sterile Disposable Antenna Kit	IIb	9	40783
SW-1425	SynchroWave LT Antenna Kit, 25cm	Sterile Disposable Antenna Kit	IIb	9	40783
TS-20	TempSure Temperature Sensor, 20cm	Sterile Disposable Temperature Sensor	IIb	9	40783

MicroThermX® Microwave Ablation Sterile Accessories

Catalog Number	Product Name	Device Type	Class	Rule	GMDN
SWST-1415	SynchroWave ST Antenna Kit, 15cm	Sterile Disposable Antenna Kit	Ila	7	40783
SWST-1420	SynchroWave ST Antenna Kit, 20cm	Sterile Disposable Antenna Kit	Ila	7	40783
SW-1415	SynchroWave LT Antenna Kit, 15cm	Sterile Disposable Antenna Kit	Ila	7	40783
SW-1420	SynchroWave LT Antenna Kit, 20cm	Sterile Disposable Antenna Kit	Ila	7	40783
SW-1425	SynchroWave LT Antenna Kit, 25cm	Sterile Disposable Antenna Kit	Ila	7	40783
TS-20	TempSure Temperature Sensor, 20cm	Sterile Disposable Temperature Sensor	Ila	7	40783