EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	*Teleflex Medical* *3015 Carrington Mill Blvd.* *Morrisville, NC 27560* *USA*
Authorized Representative Name and Address:	*Teleflex Medical* *IDA Business & Technology Park* *Dublin Rd.* *Athlone, Co. Westmeath* *Ireland*
Notified Body Name and Address:	☐ *Class I: Not Applicable* ☒ *Class Is, Im, IIa, IIb, III* SGS Belgium NV, SGS House, Noorderlaan 87 2030 Antwerp, Belgium CE 1639

☐ **Class I**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex *Insert Annex Number* and *Insert Version (ISO, BSI BS EN ISO, etc.)* ISO 13485:*Insert Publication Date*, as implemented by the European Union's Medical Devices Regulations.

☒ **Class Is, Im, IIa, IIb, III**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex *II (excluding Section 4)* and *EN* ISO 13485:*2012*, as implemented by the European Union's Medical Devices Regulations as verified by the Notified Body listed above:

Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.

Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Teleflex Medical agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

Product Name:	**Non-Sterile Heated Humidifiers (Aquatherm III)**
Classification:	**Class __IIa____ Rule ___11___**
EC Certificates No.:	**Canadian – MDSAP (ISO 13485:2016) – US18/81827522** **Europe – ISO 13485: 2016 and EN ISO 13485:2016 – US97/10878.00** **Europe – 93/42/EEC Certificate – US19/819943647.00 (CE 1639)**
Conformity Assessment Routes:	**Annex II (excluding section 4) of the MDD (93/42/EEC)**

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Product Code	Product Description	CE Distribution Date	GMDN Code
050-12D*	AquaTherm III External Adjustable Electronic Heater	September 6, 2005	12716
050-12E*	AquaTherm III External Adjustable Electronic Heater for UK	September 6, 2005	12716
050-12A*	AquaTherm III, Australia	September 6, 2005	12716

**** Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU RoHS, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment***

Name and Title of Approver:	*Nicole Schaffer* *Regulatory Affairs Manager, Respiratory*
Signature of Approver:	
Date Approved:	12-Mar-2021
Site Where Approved:	*Teleflex Medical* *3015 Carrington Mill Blvd.* *Morrisville, NC 27560 USA*

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