COVIDIEN

Declaration of Conformity

15 Hampshire St.
Mansfield, MA 02048
Tel: 508-261-8000
Fax: 508-261-8461
www.covidien.com

Technical File: **SDG-17**

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name:	**Tympanic Thermometer and Accessories**
Manufacturer:	**Covidien llc** **15 Hampshire Street** **Mansfield, MA. 02048 USA**
EC Representative:	**Covidien Ireland Limited** **IDA Business and Technology Park** **Tullamore**
Intended Use:	The Genius 2 Thermometer is intended for use in patients in acute and alternative care settings to provide temperature measurements from the tympanic membrane and equivalent measurements of oral, core and rectal temperature based on the tympanic reading. The Genius 2 Probe Covers are used with the Genius 2 Thermometer in order to protect the patients from cross contamination due to bodily fluids. The device requires that the probe cover be ejected and replaced with a new cover before a measurement is taken.
Sterility:	No *Refer to Attached Table*
Measuring Function:	Yes and No (Measurement items denoted with * on product list)
Directive Classification:	I (non-sterile) and IIa
In Accordance with Annex:	VII and II

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principals, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S. and follow conformity asssessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Date CE Marking Approved:	*Refer to Attached Table*	Current Standards to which Conformity is declared:	*Refer to Attached Table*
Reorder codes/GMDN Codes:	*Refer to Attached Table*		
EC Certificate(s):	*Refer to Attached Table*		
Notified Body Name:	TÜV SÜD Product Service GmbH Ridlerst 65 D-80339 München, Germany	Identification Number:	0123

Covidien llc hereby declares that all medical devices referenced in the attached table placed on the European Community market by the company and its subsidiaries on or after July 22, 2014 are compliant with the Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment, described in "Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011", commonly known as the EU RoHS Directive; and are therefore in compliance. Medical devices which are placed on the European Community market before July 22, 2014 are not required to (and may not) meet the Restriction of Certain Hazardous Substances as provisioned in Article 4, Paragraph 3 of the EU RoHS Directive.

COVIDIEN REGULATORY AFFAIRS MANSFIELD, MASSACHUSETTS, USA

Signature: _____ 31 AUG 2017

Nicole Camelio, Sr. Regulatory Affairs Specialist — Date

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *G1 14 11 74735 015 expires 23-Feb-2020*					
Class IIa	***Annex II***				
303000*	Genius™ 2 Tympanic Thermometer and Base	Non	Infrared patient thermometer, ear [17887]	10	7/31/2006
303000C*	Genius™ 2 Tympanic Thermometer and Base, Recalibrated	Non	Infrared patient thermometer, ear [17887]	10	7/31/2006
303000W*	Genius™ 2 Tympanic Thermometer and Base, Made in US	Non	Infrared patient thermometer, ear [17887]	10	4/2/2007
303079*	Genius™ 2 Tympanic Thermometer and Base, Refurbished	Non	Infrared patient thermometer, ear [17887]	10	4/2/2007
EC Certificate: *Self Certified*					
Class I (non-sterile)	***Annex VII***				

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Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*					
Class I (non-sterile)	***Annex VII***				
303030	Genius™ 2 Tympanic Probe Covers	Non	Electronic thermometer probe cover [13116]	5	7/31/2006
31424784	Argyle™ Hydrogel Temperature Probe Cover, Duck & Bear Shaped, Small	Non	Electronic thermometer probe cover [13116]	5	3/5/2012
31424792	Argyle™ Hydrogel Temperature Probe Cover, Duck & Bear Shaped, Large	Non	Electronic thermometer probe cover [13116]	5	3/5/2012

Techfile: SDG-17

Standards to Which Conformity is Declared:

Standard Name:	Standard Title:	Version:
ASTM E 1104	Specification for Clinical Thermometers Probe Covers and Sheaths	98
ASTM E 1965*	Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	98
EN 12470-5:2003*	Clinical Thermometers - Part 5: Performance of Infra-red Ear Thermometers (with Maximum Device)	2003
EN 60601-1:2006	Medical Electrical Equipment – General Requirements for Safety	2006/AC:2010
EN 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2007/AC:2010
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices	2008
ISO 10993-1:2009	ISO 10993-1:2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process	2009/AC:2010
ISTA 2A	ISTA Preshipment Testing Procedures - Combination Tests for packaged products weighing 150lbs (68kg) or less	2011
EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	2012/AC:2012
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices	2012

Unless otherwise indicated with an *, full conformance to listed standards is assumed.

Standard Name:	Standard Title:	Version:
EN 980:2008	Symbols for Use in the Labelling of Medical Devices	2008

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