COVIDIEN

Declaration of Conformity

15 Hampshire St.
Mansfield, MA 02048
Tel: 508-261-8000
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Technical File: **RE00135119**

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:	**Genius 3 Tympanic Thermometer and Base**
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 3 Tympanic 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 and rectal temperature based on the tympanic reading.
Sterility:	No *Refer to Attached Table*
Measuring Function:	No
Directive Classification:	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.

Signature: Kerri Laplaca April 17, 2018

Kerri Laplaca, Sr. Regulatory Affairs Specialist — Date

COVIDIEN REGULATORY AFFAIRS MANSFIELD, MASSACHUSETTS, USA

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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***			
303013	Genius 3 Tympanic Thermometer and Base	Non	Thermometer, infrared, ear [17887]	10	4/17/2018

Standards List for

RE00135119 - Genius™ 3 Tympanic Thermometer and Base

Standards to Which Conformity is Declared:

STANDARD:	STANDARD TITLE:	VERSION:
ISO 80601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	2017
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2006/A1:2013
EN 60601-1-2	Medical electrical equipment - Part 1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	2015
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010/A1:2015
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical	2015
EN 62366-1	Medical devices - Application of usability engineering to medical devices	2015
EN 62304	Medical device software - Software life-cycle processes	2006/A1:2015
ISTA 2A	ISTA Partial Simulation Performance Tests for Packaged-Products 150lbs (68kg) or less	2011
EN 1041	Information supplied by the manufacturer of medical devices	2008/A1:2013
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/AC:2016
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012

Unless otherwise indicated, full conformance to listed standards is assumed