COVIDIEN

Declaration of Conformity

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

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, Ireland

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

The manufacturer has exclusive responsibility for this Declaration of Conformity.

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*

EC Certificate(s): *Refer to Attached Table*

Reorder codes/GMDN Codes: *Refer to Attached Table*

Notified Body Name: TÜV SÜD Product Service GmbH
Ridlerstraße 65
D-80339 München, Germany

Identification Number: 0123

REGULATORY AFFAIRS COVIDIEN MANSFIELD, MASSACHUSETTS, USA

Signature: Kerri Laplaca

Kerri Laplaca, Regulatory Affairs Manager

March 5, 2020
Date

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *G1 074735 0083*						
Class IIa		***Annex II excluding (4)***				
303013	Genius 3 Tympanic Thermometer and Base	Yes	Non	Infrared patient thermometer, ear [17887]	10	4/17/2018

Standards List for

RE00135119 – Genius™ 3Tympanic Thermometer

Standards to Which Conformity is Declared:

STANDARD:	STANDARD TITLE:	VERSION:
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
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 1041	Information supplied by the manufacturer of medical devices	2008/A1:2013
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	2005/A1:2012
EN 60601-1-2	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/A1:2013
IEC 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 Systems used in the home healthcare environment	2015
EN 62304	Medical device software - Software life-cycle processes	2006/A1:2015
EN 62366-1	Medical devices - Application of usability engineering to medical devices	2015
IEC 60529	Degrees of protection provided by enclosures (IP Code)	1989/AMD1:1999/AMD2:2013

Unless otherwise indicated, full conformance to listed standards is assumed