



Declaration of Conformity

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Mansfield, MA 02048
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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, Ireland**

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 Probe Covers can be used with the Genius 2 Thermometer and Genius 3 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: No

Directive Classification: I (non-sterile) and 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 assessment 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 Identification Number: 0123
Ridlerstraße 65
D-80339 München, Germany



Signature: *Kalaplaca*

Kerri LaPlaca, Regulatory Affairs Manager

March 13, 2020

Date

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	Ila	Annex II excluding (4)				
303000C	Genius™ 2 Tympanic Thermometer and Base, Recalibrated	Yes	Non	Infrared patient thermometer, ear [17887]	10	7/31/2006
303079	Genius™ 2 Tympanic Thermometer and Base, Refurbished	Yes	Non	Infrared patient thermometer, ear [17887]	10	4/2/2007

EC Certificate: Self Certified

Class	I (non-sterile/non-measuring)	Annex VII				
303030	Genius™ Tympanic Probe Covers	No	Non	Electronic thermometer probe cover [13116]	5	7/31/2006
31424784	Argyle™ Hydrogel Temperature Probe Cover, Duck & Bear Shaped, Small	No	Non	Basic adhesive skin tape [16866]	1	3/5/2012

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)		Annex VII			
31424792	Argyle™ Hydrogel Temperature Probe Cover, Duck & Bear Shaped, Large	No	Non	Basic adhesive skin tape [16866]	1	3/5/2012