

Technical File: **TF-118**

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: **Skin Cleansing Alcohol Prep Pad**

Manufacturer: **Covidien Inc**
15 Hampshire Street
Mansfield, MA. 02048 USA

EC Representative: **Covidien Ireland Limited**
IDA Business and Technology Park
Tullamore, Ireland

Intended Use: **The prep pad is saturated with alcohol for cleansing skin.**

Sterility: **Yes**

Measuring Function: **No**

Directive Classification: **I (measuring/sterile)**

In Accordance with Annex: **V and VII**



Refer to Attached Table

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: *Keith Gattozzi*
Keith Gattozzi, Regulatory Affairs Specialist

16-Mar-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: G2S 074735 0084						
Class	I (sterile/non-measuring)	Annex VII and V				
6818-1	Webcol™ Skin Cleansing Alcohol Prep, 2 Ply, Medium	No	Gamma	Skin-cleaning wipe, sterile [61695]	1	7/25/2011