

Declaration of Conformity

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

Technical File: **TF-01**

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: **Woundcare Products & Surgical Sponges**

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

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



Intended Use: Used as a mechanical barrier to protect various wounds and to absorb wound exudates. The type of wounds may include burns, surgical incisions, skin grafts, abrasions, and other superficial wounds. Surgical sponges are used during surgery to swab fluid within the incision cavity. Perineal Cold Pads are intended to provide cooling comfort to the perineum postpartum and also to absorb Lochia.

Sterility: Yes and No *Refer to Attached Table*

Measuring Function: No

Directive Classification: I (non-sterile/non-measuring), I (sterile/non-measuring) and IIa

In Accordance with Annex: VII, V and II excluding (4)

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
Ridlerstraße 65
D-80339 München, Germany

Identification Number: 0123

Signature:

Maria Rao
Maria Rao, Regulatory Affairs Manager

June 10, 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)				
1069	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled, Jumbo, 2" (5.1 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/3/2002
2-6214	Kerlix™ Laparotomy Sponges Radiopaque, 4-Ply 16" x 25" (41 cm x 63 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
2-6222	Kerlix™ X-Ray Detectable Laparotomy Sponges, 4 Ply, 17" x 16" (43.2 cm x 40.6 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
2-6235	Kerlix™ Laparotomy Sponges Radiopaque, 8-Ply 16" x 3" (41 cm x 7 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
2949	Kerlix™ X-Ray Detectable Round Sponges, X-Large 1-5/8" (4.1 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998
4031	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 17" x 26" (43.2 cm x 66 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
4034	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack 16" x 17" (40.6 cm x 43.2 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998

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)				
4037	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 8" x 32" (20.3 cm x 81.3 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
4334	Vistec™ X-Ray Detectable Sponges, 32 Ply 4" x 3- 1/2" (10.2 cm x 8.9 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998
6297	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Medium, 1- 5/16" (3.3 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/3/2002
6365	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Large, 1- 1/8" (2.9 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/3/2002
6449	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled, X-Large, 1- 5/8" (4.1 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998
6493	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Super, 1- 3/4" (4.4 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	10/2/2002
6591	Vistec™ X-Ray Detectable Sponges, Round All-Gauze Large, 1- 1/2" (3.8 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998

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)				
6653	Vistec™ X-Ray Detectable Sponges, Round All-Gauze X-Large, 1- 5/8" (4.1 cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	11/30/2001
7114	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998
7148	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	No	Non	Radiopaque woven surgical sponge, non-sterile [58802]	7	4/21/1998
7317	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
7631	Curity™ Plain Packing Strip 1/4" x 15' (0.6 cm x 4.6 m)	No	Gamma	Gauze strip [48128]	7	7/26/2001
7632	Curity™ Plain Packing Strip 1/2" x 15' (1.3 cm x 4.6 m)	No	Gamma	Gauze strip [48128]	7	7/26/2001
7633	Curity™ Plain Packing Strip 1" x 15' (2.5 cm x 4.6 m)	No	Gamma	Gauze strip [48128]	7	7/26/2001

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)				
7634	Curity™ Plain Packing Strip 2" x 15' (5.1 cm x 4.6 m)	No	Gamma	Gauze strip [48128]	7	7/26/2001
8062	Kerlix™ X-Ray Detectable Laparotomy Sponges, Radiopaque, 4 Ply, Stretched, Unfolded, 16" x 25" (41 cm x 63 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998
8095	Kerlix™ X-Ray Detectable Laparotomy Sponges, 8 Ply, Stretched, Unfolded, 16" x 3" (41 cm x 7 cm)	No	EO	Radiopaque woven surgical sponge, sterile [38496]	7	4/21/1998

EC Certificate: G2S 074735 0084

Class	I (sterile/non-measuring)	Annex VII and V				
10057	Kerlix Gauze Roll 11.4 cm x 3.7 m Stretched	No	EO	Woven gauze roll, sterile [48127]	1	12/31/2013
1806	Curity™ Gauze Sponges 8 Ply 2" x 2" (5.1 cm x 5.1 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001

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				
1903	Curity™ Gauze Sponges 12 Ply 3" x 3" (7.6 cm x 7.6 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001
1967	Curity™ Multi Trauma Dressing 10" x 30" (25.4 cm x 76.2 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
2187	Curity™ Gauze Sponges, 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001
2283	Webril™ Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2394	Webril™ Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2502	Webril™ Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2554	Webril™ Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001

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				
2585	Kerlix™ Super Sponges, Medium, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
2666	Webril™ Cotton Undercast Padding, Crimped Finish, 2" x 12' (5.1 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2754	Webril™ Cotton Undercast Padding, Crimped Finish, 3" x 12' (7.6 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2847	Webril™ Cotton Undercast Padding, Crimped Finish 4" x 12' (10.2 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
2913	Curity™ Cover Sponges 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
2944	Webril™ Cotton Undercast Padding, Crimped Finish 6" x 12' (15.2 cm x 3.7 m)	No	EO	Cast stockinette [10669]	4	7/26/2001
3033	Curity™ Gauze Sponges 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001

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				
3157	Curity™ Cover Sponges, 4" x 3" (10.2 cm x 7.6 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
3381	Curity™ Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001
3913	Curity™ Heavy Drainage Pack	No	EO	Wound-nonadherent dressing, absorbent, sterile [46854]	4	7/26/2001
3967	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	7/26/2001
3968	Curity™ Gauze Sponges 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
397110	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	7/26/2001
397310	Curity™ Gauze Sponges 16 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998

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				
4588	Kerlix™ Sponges, 16 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
5072	Kerlix™ Sponges, 12 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001
6120	Kerlix™ Sponges, 12 Ply, 4" x 4" (10.2cm x 10.2cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
6132	Curity™ Gauze Pad 3" x 3" (7.6 cm x 7.6 cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001
6241	Curity™ I.V. Sponges, 2" x 2" (5.1 cm x 5.1 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
6242P	Curity™ Drain Sponges, 4" x 4" (10.2cm x 10.2cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	4/21/1998
6309	Curity™ Gauze Pad 4" x 4" (10.2cm x 10.2cm)	No	Steam	Woven gauze pad, sterile [48134]	4	7/26/2001

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				
6318	Curity™ Gauze Sponges, 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
6715	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m)	No	EO	Woven gauze roll, sterile [48127]	4	4/21/1998
6716	Kerlix™ Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	No	EO	Woven gauze roll, sterile [48127]	4	7/26/2001
6720	Kerlix™ Bandage Roll 100% Cotton, 6 Ply Small, 2- 1/4" x 9' (5.7 cm x 2.7 m)	No	EO	Woven gauze roll, sterile [48127]	4	7/26/2001
6725	Kerlix™ Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	No	EO	Woven gauze roll, sterile [48127]	4	7/26/2001
6730	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m)	No	EO	Woven gauze roll, sterile [48127]	4	4/21/1998
6939	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998

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				
7083	Curity™ Dressing Sponges, 6 Ply, 4" x 3" (10.2 cm x 7.6 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	4/21/1998
7084	Curity™ Dressing Sponges, 6 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	4/21/1998
7085	Curity™ Dressing Sponges, 6 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	4/21/1998
7086	Excilon™ Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	4/21/1998
7087	Excilon™ I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	4/21/1998
7196D	Dermacea™ Abdominal Pad 5" x 9" (12.7cm x 22.9cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	1/8/2007
7197D	Dermacea™ Abdominal Pad 7-1/2" x 8" (19.1cm x 20.3cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	12/19/2006

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				
7198D	Dermacea™ Abdominal Pad 8" x 10" (20.3cm x 25.4cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	1/5/2007
7310	Kerlix™ Super Sponges, Medium, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	No	EO	Woven gauze pad, sterile [48134]	4	4/21/1998
7605	Curity™ Gauze Sponges 16 Ply 4" x 4" (10.2.cm x 10.2 cm)	No	EO	Woven gauze pad, sterile [48134]	4	7/26/2001
7880	Kerlix™ Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched	No	EO	Woven gauze roll, sterile [48127]	4	4/21/1998
7884	Kerlix™ Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	No	EO	Woven gauze pad, sterile [48134]	4	7/26/2001
7911	Curity Burn Dressing, USP Type VII Gauze 10 Ply 18" x 18" (45.7cm x 45.7cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	7/26/2001
7960	Curity Burn Dressing, USP Type VII Gauze 50 Ply 18" x 18" (45.7cm x 45.7cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	7/26/2001

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				
8042	Curity™ All Purpose Sponges Nonwoven, 4 Ply 2" x 2" (5.1 cm x 5.1 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
8043	Curity™ All Purpose Sponges Nonwoven, 4 Ply 3" x 3" (7.6 cm x 7.6 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
8044	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
8045	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	7/26/2001
8046	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 3" (10.2 cm x 7.6 cm)	No	Steam	Non-woven gauze pad, sterile [48131]	4	7/26/2001
8047	Curity™ All Purpose Sponges Nonwoven, 4 Ply Soft Pouch 4" x 4" (10.2 cm x 10.2 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	7/26/2001
9190A	Curity™ Abdominal Pad with Wet Proof Barrier, 5" x 9" (12.7 cm x 22.9 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	1/8/2007

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				
9192A	Curity™ Abdominal Pad with Wet Proof Barrier 7-1/2" x 8" (19.1 cm x 20.3 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	12/19/2006
9194A	Curity™ Abdominal Pad with Wet Proof Barrier, 8" x 10" (20.3 cm x 25.4 cm)	No	EO	Non-woven gauze pad, sterile [48131]	4	1/5/2007
ES 101-LT	Eye Shield, Left	No	Gamma	Eye pad [11661]	4	8/6/2008
ES 101-RT	Eye Shield, Right	No	Gamma	Eye pad [11661]	4	8/6/2008

EC Certificate: Self Certified

Class	I (non-sterile/non-measuring)	Annex VII				
1143	Curity™ Mesh Gauze Bandage Roll, 1" x 30' (2.5 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	1/29/2002

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
1167	Kerlix™ Super Sponges, Medium 6" x 6- 3/4" (15.2 cm x 17.1 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	4/21/1998
1272	Kerlix™ Super Sponges, Large 7- 3/4" x 8- 3/4" (19.7 cm x 22.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	4/21/1998
1334	Curity™ Mesh Gauze Bandage Roll, 2" x 30' (5.1 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	1/29/2002
1418	Webril™ Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998
1522	Curity™ Mesh Gauze Bandage Roll, 3" x 30' (7.6 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	1/29/2002
1700	Curity™ Cover Sponges, 3" x 3" (7.6 cm x 7.6 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001
1713	Curity™ Cover Sponges, 4" x 3" (10.2 cm x 7.6 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
1792	Curity™ Cover Sponges, 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001
1801	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply, Small, 2- 1/4" x 9' (5.7 cm x 2.7 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	4/21/1998
1824	Curity™ Mesh Gauze Bandage Roll, 4" x 30' (10.2 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	1/29/2002
1892	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	4/21/1998
2059	Webril™ Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998
2438	Curity™ Gauze Sponges, 32 Ply 4" x 3- 1/2" (10.2 cm x 8.9 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	7/26/2001
2556	Curity™ Gauze Sponges, 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	7/26/2001

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
2733	Curity™ Gauze Sponge, 16 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	4/21/1998
3041	Curity™ Sponges, Cellulose Filled, 2" x 2" (5.1 cm x 5.1 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	4/21/1998
3175	Webril™ Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998
3208	Curity™ Sponges, Cellulose Filled, 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	6/11/2001
3250	Curity™ Mesh Gauze Bandage Roll, 3" x 30' (7.6 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	3/4/2002
3324	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply, Large, 4- 1/2" x 4-1/8 yd (11.4 cm x 3.7 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	7/26/2001
3489	Webril™ Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
4032	Kerlix™ Sponges 12 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	7/26/2001
4095	Webril™ Cotton Undercast Padding, Crimped Finish, 2" x 12' (5.1 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	7/26/2001
4152	Webril™ Cotton Undercast Padding, Crimped Finish, 3" x 12' (7.6 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998
4221	Webril™ Cotton Undercast Padding, Crimped Finish, , 4" x 12' (10.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	4/21/1998
4519	Webril™ Cotton Undercast Padding, Crimped Finish, 6" x 12' (15.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	7/26/2001
5042	Kerlix™ Sponges, 16 Ply, 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	7/26/2001
6021	Curity™ Mesh Gauze Bandage Roll, 4" x 30' (10.2 cm x 9.1 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	1/29/2002

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
6035	Kerlix™ Super Sponges, X-Large, 9- 3/4" x 10- 3/4" (24.8 cm x 27.3 cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	4/21/1998
6196D	Dermacea™ Abdominal Pad 5" x 9" (12.7cm x 22.9cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/8/2007
6197D	Dermacea™ Abdominal Pad 7-1/2" x 8" (19.1cm x 20.3cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	12/19/2006
6198D	Dermacea™ Abdominal Pad 8" x 10" (20.3cm x 25.4cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/5/2007
6242	Curity™ Synthetic Undercast Padding, 2" x 12' (5.1 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	9/14/2001
6243	Curity™ Synthetic Undercast Padding, 3" x 12' (7.6 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	9/14/2001
6244	Curity™ Synthetic Undercast Padding, 4" x 12' (10.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	9/14/2001

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
6246	Curity™ Synthetic Undercast Padding, 6" x 12' (15.2 cm x 3.7 m)	No	Non	Cast stockinette [10669]	4	9/14/2001
6735	Kerlix™ Bandage Roll, 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	No	Non	Woven gauze roll, non-sterile [48126]	4	7/26/2001
7267	Curity™ Gauze Sponges, 16 Ply 4" x 3" (10.2cm x 7.6cm)	No	Non	Woven gauze pad, non-sterile [48133]	4	7/26/2001
7882	Kerlix™ Gauze Roll, 6 Ply, Large 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched	No	Non	Woven gauze roll, non-sterile [48126]	4	4/24/2001
8190A	Curity™ Abdominal Pad with Wet Proof Barrier, 5" x 9" (12.7 cm x 22.9 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/8/2007
8192A	Curity™ Abdominal Pad with Wet Proof Barrier, 7-1/2" x 8" (19.1 cm x 20.3cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	12/19/2006
8194A	Curity™ Abdominal Pad with Wet Proof Barrier, 8" x 10" (20.3 cm x 25.4 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/5/2007

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified						
Class	I (non-sterile/non-measuring)	Annex VII				
9022	Curity™ All Purpose Sponges Non-Woven, 4 Ply 2" x 2" (5.1 cm x 5.1 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001
9023	Curity™ All Purpose Sponges Non-Woven, 4 Ply 3" x 3" (7.6 cm x 7.6 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001
9024	Curity™ All Purpose Sponges Non-Woven, 4 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	7/26/2001
9132	Curity™ All Purpose Sponges Nonwoven, 3 Ply 2" x 2" (5.1 cm x 5.1 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/29/2002
9134	Curity™ All Purpose Sponges Nonwoven, 3 Ply 4" x 4" (10.2 cm x 10.2 cm)	No	Non	Non-woven gauze pad, non-sterile [48130]	4	1/29/2002