

DECLARATION OF CONFORMITY



We, Covidien llc, declare that the products covered in this Declaration of Conformity meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

Declaration of Conformity Number	TF-01, Revision 56
Technical Documentation Number	TF-01
Manufacturer's Name	Covidien llc
Manufacturer's Address	15 Hampshire Street Mansfield, MA 02048
Authorized Representative's Name and Address	Covidien Ireland Limited IDA Business and Technology Park, Tullamore, Ireland
Notified body's Name and Identification Number	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
CE Certificate Number	G1 074735 0083 (Class IIa) G2S 074735 0084 (Class I, Sterile)
Product Category	Wound Management
GMDN	Cast stockinette [10669] Radiopaque woven surgical sponge, sterile [38496] Gauze roll, sterile [48127] Gauze strip [48128] Non-woven gauze pad, sterile [48131] Woven gauze pad, sterile [48134] Radiopaque woven surgical sponge, non-sterile [58802]
Product Code, Trade Name and Description	Refer to Attachment 1.
Intended Purpose	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.
Classification and Rule	Refer to Attachment 1.
Where appropriate, add applicable Union legislation	N/A
Conformity Assessment	Annex II excluding (4) for Class IIa Annex V and VII for Class I (Sterile/Non-Measuring)

SIGNATURE SECTION

This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.

Place of Issue	Mansfield, MA 02048 USA	
Signature/ Date	<i>Charmaine Wong</i> <small>Electronically signed by: Charmaine Wong Reason: Approved Date: May 25, 2023 11:24 GMT+8</small>	May 25, 2023
Name and Function	Charmaine Wong Siting, Regulatory Affairs	

ATTACHMENT 1

Product Code List			
Product Code	Trade Name and Description	GMDN	Classification and Rule
1069	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled, Jumbo, 2" (5.1 cm)	58802	Class IIa, Rule 7
2949	Kerlix™ X-Ray Detectable Round Sponges, X-Large 1-5/8" (4.1 cm)	58802	Class IIa, Rule 7
4334	Vistec™ X-Ray Detectable Sponges, 32 Ply 4" x 3- 1/2" (10.2 cm x 8.9 cm)	58802	Class IIa, Rule 7
6297	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Medium, 1- 5/16" (3.3 cm)	58802	Class IIa, Rule 7
6365	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Large, 1- 1/8" (2.9 cm)	58802	Class IIa, Rule 7
6449	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled, X-Large, 1- 5/8" (4.1 cm)	58802	Class IIa, Rule 7
6493	Vistec™ X-Ray Detectable Sponges, Round Cotton-Filled Super, 1- 3/4" (4.4 cm)	58802	Class IIa, Rule 7
6591	Vistec™ X-Ray Detectable Sponges, Round All-Gauze Large, 1- 1/2" (3.8 cm)	58802	Class IIa, Rule 7
6653	Vistec™ X-Ray Detectable Sponges, Round All-Gauze X-Large, 1- 5/8" (4.1 cm)	58802	Class IIa, Rule 7
7114	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	58802	Class IIa, Rule 7
7148	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	58802	Class IIa, Rule 7
7317	Vistec™ X-Ray Detectable Sponges, 16 Ply 4" x 4" (10.2cm x 10.2cm)	38496	Class IIa, Rule 7
7631	Curity™ Plain Packing Strip 1/4" x 15' (0.6 cm x 4.6 m)	48128	Class IIa, Rule 7
7632	Curity™ Plain Packing Strip 1/2" x 15' (1.3 cm x 4.6 m)	48128	Class IIa, Rule 7
7633	Curity™ Plain Packing Strip 1" x 15' (2.5 cm x 4.6 m)	48128	Class IIa, Rule 7
7634	Curity™ Plain Packing Strip 2" x 15' (5.1 cm x 4.6 m)	48128	Class IIa, Rule 7
7086	Excilon Drain Sponges, 6 Ply, 4" x 4" (10.2cm x 10.2cm)	48131	Class I (S/NM), Rule 4
7087	Excilon I.V. Sponges, 6 Ply, 2" x 2" (5.1cm x 5.1cm)	48131	Class I (S/NM), Rule 4
3381	Curity Gauze Pads 2" x 2" (5.1 cm x 5.1 cm)	48134	Class I (S/NM), Rule 4
6309	Curity Gauze Pad 4" x 4" (10.2cm x 10.2cm)	48134	Class I (S/NM), Rule 4
6716	Kerlix Bandage Roll, 100% Cotton, 8 Ply, Large, 4-1/2" x 9.3' (11.4 cm x 2.8 m)	48127	Class I (S/NM), Rule 4
6725	Kerlix Bandage Roll 100% Cotton, 6 Ply Medium, 3-7/16" x 3-3/16' (8.6 cm x 3.3 m)	48127	Class I (S/NM), Rule 4
7880	Kerlix Gauze Roll, 6 Ply, Large, 4-1/2" x 4-1/8 yd (11.4 cm x 3.7 m) Stretched	48127	Class I (S/NM), Rule 4
7884	Kerlix Super Sponges, 6" x 6-3/4" (15.2 cm x 17.1 cm)	48134	Class I (S/NM), Rule 4
10057	I Kerlix - Gauze Roll	48127	Class I (S/NM), Rule 1
2283	Webiril Cotton Undercast Padding, Regular Finish, 2" x 12' (5.1 cm x 3.7 m)	10669	Class I (S/NM), Rule 4

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2394	Webril Cotton Undercast Padding, Regular Finish, 3" x 12' (7.6 cm x 3.7 m)	10669	Class I (S/NM), Rule 4
2502	Webril Cotton Undercast Padding, Regular Finish, 4" x 12' (10.2 cm x 3.7 m)	10669	Class I (S/NM), Rule 4
2554	Webril Cotton Undercast Padding, Regular Finish, 6" x 12' (15.2 cm x 3.7 m)	10669	Class I (S/NM), Rule 4
2585	Kerlix Super Sponges, Medium, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	48134	Class I (S/NM), Rule 4
7310	Kerlix Super Sponges, Medium, 6" x 6- 3/4" (15.2 cm x 17.1 cm)	48134	Class I (S/NM), Rule 4
6132	Curity Gauze Pad 3" x 3" (7.6 cm x 7.6 cm)	48134	Class I (S/NM), Rule 4
6715	Kerlix Bandage Roll, 100% Cotton, 6 Ply Large, 4-1/2" x 4- 1/8 yd (11.4 cm x 3.7 m)	48127	Class I (S/NM), Rule 4
6730	Kerlix Bandage Roll, 100% Cotton, 6 Ply Large, 4-1/2" x 4- 1/8 yd (11.4 cm x 3.7 m)	48127	Class I (S/NM), Rule 4
6241	Curity I.V. Sponges, 2" x 2" (5.1 cm x 5.1 cm)	48131	Class I (S/NM), Rule 4
6720	Kerlix Bandage Roll 100% Cotton, 6 Ply Small, 2- 1/4" x 9' (5.7 cm x 2.7 m)	48127	Class I (S/NM), Rule 4
1806	Curity™ Gauze Sponges 8 Ply 2" x 2" (5.1 cm x 5.1 cm)	48134	Class I (S/NM), Rule 4
1903	Curity™ Gauze Sponges 12 Ply 3" x 3" (7.6 cm x 7.6 cm)	48134	Class I (S/NM), Rule 4
2187	Curity™ Gauze Sponges, 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
2913	Curity™ Cover Sponges 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
3033	Curity™ Gauze Sponges 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
3157	Curity™ Cover Sponges, 4" x 3" (10.2 cm x 7.6 cm)	48131	Class I (S/NM), Rule 4
3967	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
3968	Curity™ Gauze Sponges 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
4588	Kerlix™ Sponges, 16 Ply, 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
5072	Kerlix™ Sponges, 12 Ply, 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
6120	Kerlix™ Sponges, 12 Ply, 4" x 4" (10.2cm x 10.2cm)	48134	Class I (S/NM), Rule 4
6318	Curity™ Gauze Sponges, 8 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
6939	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
7083	Curity™ Dressing Sponges, 6 Ply, 4" x 3" (10.2 cm x 7.6 cm)	48131	Class I (S/NM), Rule 4
7084	Curity™ Dressing Sponges, 6 Ply, 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
7085	Curity™ Dressing Sponges, 6 Ply, 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
7605	Curity™ Gauze Sponges 16 Ply 4" x 4" (10.2.cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
8042	Curity™ All Purpose Sponges Nonwoven, 4 Ply 2" x 2" (5.1 cm x 5.1 cm)	48131	Class I (S/NM), Rule 4
8043	Curity™ All Purpose Sponges Nonwoven, 4 Ply 3" x 3" (7.6 cm x 7.6 cm)	48131	Class I (S/NM), Rule 4

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8044	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
8045	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
8046	Curity™ All Purpose Sponges Nonwoven, 4 Ply 4" x 3" (10.2 cm x 7.6 cm)	48131	Class I (S/NM), Rule 4
8047	Curity™ All Purpose Sponges Nonwoven, 4 Ply Soft Pouch 4" x 4" (10.2 cm x 10.2 cm)	48131	Class I (S/NM), Rule 4
397110	Curity™ Gauze Sponges 12 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
397310	Curity™ Gauze Sponges 16 Ply 4" x 4" (10.2 cm x 10.2 cm)	48134	Class I (S/NM), Rule 4
6242P	Curity™ Drain Sponges, 4" x 4" (10.2cm x 10.2cm)	48131	Class I (S/NM), Rule 4
7196D	Dermacea™ Abdominal Pad 5" x 9" (12.7cm x 22.9cm)	48131	Class I (S/NM), Rule 4
7197D	Dermacea™ Abdominal Pad 7-1/2" x 8" (19.1cm x 20.3cm)	48131	Class I (S/NM), Rule 4
7198D	Dermacea™ Abdominal Pad 8" x 10" (20.3cm x 25.4cm)	48131	Class I (S/NM), Rule 4
9190A	Curity™ Abdominal Pad with Wet Proof Barrier, 5" x 9" (12.7 cm x 22.9 cm)	48131	Class I (S/NM), Rule 4
9192A	Curity™ Abdominal Pad with Wet Proof Barrier 7-1/2" x 8" (19.1 cm x 20.3 cm)	48131	Class I (S/NM), Rule 4
9194A	Curity™ Abdominal Pad with Wet Proof Barrier, 8" x 10" (20.3 cm x 25.4 cm)	48131	Class I (S/NM), Rule 4








TF-01 - DoC Update

Final Audit Report

2023-05-25

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-  Document created by vani.bala@cardinalhealth.com
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2023-05-25 - 3:23:11 AM GMT
-  Signer charmaine.wongsiting@cardinalhealth.com entered name at signing as Charmaine Wong
2023-05-25 - 3:24:01 AM GMT
-  Charmaine Wong (charmaine.wongsiting@cardinalhealth.com) authenticated with Adobe Acrobat Sign.
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-  Document e-signed by Charmaine Wong (charmaine.wongsiting@cardinalhealth.com)
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