Sterile Dressings, Declaration of Conformity

MANUFACTURER	
Name of Company	**Address**
Centurion Medical Products, LP	100 Centurion Way Williamston, MI 48895 USA
SRN	US-MF-000002554

EU AUTHORIZED REPRESENTATIVE	
Name of Company	**Address**
Medline International France SAS	5 Rue Charles Lindbergh, 44110 Châteaubriant France
SRN	FR-AR-000001814

UK RESPONSIBLE PERSON	
Name of Company	**Address**
Medline Industries Ltd	3rd Floor Quayside Wilderspool Business Park Greenalls Avenue Warrington WA4 6HL United Kingdom

PRODUCT IDENTIFICATION	
Product Name	**Product Code / Catalog Number**
Sterile Dressings	Product Codes attached in Schedule 1
Basic UDI-DI	
0653160CMPDressingsSZH	
Intended Purpose	
Sterile Dressings are adhesive devices intended to provide an occlusive barrier between the patient and insertion site of the catheter to wick moisture, absorb minor exudates, and to secure objects to the skin.	

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EUROPEAN UNION REGULATIONS	
We herewith declare under our sole responsibility the above-mentioned products meet the provisions of the following EU Regulations and/or Council Directive(s) as transposed into national laws.	
Applicable Directive	Council Directive 93/42/EEC
Conformity Assessment Procedure	Annex V
Risk Class	Class I
Classification	Rule 4, Annex IX
Notified Body	BSI, The Netherlands B.V. (2797) Say Building John M. Keynesplien 9 1066 EP Amsterdam
CE Certificate	CE 502193
Applicable Standards and/or Common Specifications	Included in the Sterile Dressing technical file
Statement of Amendment	This Declaration of Conformity for European Medical Devices Directive 93/42/EEC has been re-issued and signed for administrative purposes. We confirm these products were listed on a valid CE Declaration of Conformity prior to the Date of Application (26 May 2021) of Regulation (EU) 2017/745 and may continue to be placed on the market in compliance with Article 120 Transitional Provision of the Regulation.

COMPANY REPRESENTATIVE: Sheri Deisler, Manager, Regulatory Affairs

SIGNATURE: Sheri Deisler

Digitally signed by Sheri Deisler
DN: cn=Sheri Deisler, o=Centurion Medical Products, LP a division of Medline Industries, LP, ou=Quality-Regulatory, email=sdeisler@medline.com, c=US
Date: 2022.02.22 14:01:42 -05'00'

DATE:

UNITED KINGDOM REGULATIONS	
We herewith declare under our sole responsibility the above-mentioned products meet the provisions of the Medical Devices Regulations 2002 as amended by the Medical Devices Regulations 2020.	
Risk Class	Class I
UKCA Route to Conformity	Part II of UK MDR 2002, Annex II
UKCA Certificate	759016
UKCA Approved Body	BSI, The United Kingdom (0086) Kitemark Court Davy Avenue Milton Keynes MK5 8PP
UK Designated Standards	Same as EU Standards

COMPANY REPRESENTATIVE: Sheri Deisler, Manager, Regulatory Affairs

SIGNATURE:

DATE: Sheri Deisler

Digitally signed by Sheri Deisler
DN: cn=Sheri Deisler, o=Centurion Medical Products, LP a division of Medline Industries, LP, ou=Quality-Regulatory, email=sdeisler@medline.com, c=US
Date: 2022.02.22 14:03:03 -05'00'

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Schedule 1 to the Declaration of Conformity

Component Number	Object Description
LVAD66UXT	DRIVELINE DRESSING
LVAD66UXT-6	DRIVELINE DRESSING
SCVP44XT	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, 4 ½”X4 ½”
SCVP44XT-6	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, 4 ½”X4 ½”
SCP44VXT	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, TAPE STRIP, 4 ½”X4 ½”
SCP44VXT-6	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, TAPE STRIP, 4 ½”X4 ½”
SCVP66XT	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, 5 ½”X6 ½”
SCVP66XT-6	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, 5 ½”X6 ½”
SCP66VXT	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, TAPE STRIP, 5 ½”X6 ½”
SCP66VXT-6	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, TAPE STRIP, 5 ½”X6 ½”
SCP66VXT2	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, (2) TAPE STRIPS, 5 ½”X6 ½”
SCP66VXT2-6	SECUREVIEW PORT WINDOW DRESSING WITH ADHESIVE FREE ZONE, (2) TAPE STRIPS, 5 ½”X6 ½”
SV117UDT	SORBAVIEW SHIELD NANO SECUREMENT SYSTEM, TAPE STRIP, 2”X2 ¼”
SV118UDT	SORBAVIEW SHIELD NANO SECUREMENT SYSTEM, TAPE STRIP, 2”X2 ½”
SV118UDT-6	SORBAVIEW SHIELD NANO SECUREMENT SYSTEM, TAPE STRIP, 2”X2 ½”
SV15XT	SORBAVIEW 2000 WINDOW DRESSING, 2”X1 ¾”
SV15XT-6	SORBAVIEW 2000 WINDOW DRESSING, 2”X1 ¾”
SV15ZXT	SORBAVIEW 2000 WINDOW DRESSING, HUBGUARD, 2”X1 ¾”
SV226UDT	SORBAVIEW SHIELD MICRO SECUREMENT SYSTEM, TAPE STRIP, 2 ¼”X2 ⅝”
SV226UDT-6	SORBAVIEW SHIELD MICRO SECUREMENT SYSTEM, TAPE STRIP, 2 ¼”X2 ⅝”
SV233DBSXT	SORBAVIEW SHIELD PLUS IV, SORBAVIEW SHIELD SECUREMENT SYSTEM, HUBGUARD, TAPE STRIP
SV233UDT	SORBAVIEW SHIELD PERIPHERAL, SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY)
SV233UDT-6	SORBAVIEW SHIELD PERIPHERAL, SECUREMENT SYSTEM, TAPE STRIP
SV254AFXT	SORBAVIEW SHIELD SMALL, SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 2 ½”X4”
SV254AFXT-6	SORBAVIEW SHIELD SMALL, SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 2 ½”X4”
SV254DBSXT	SORBAVIEW SHIELD PLUS IV, SORBAVIEW SHIELD SECUREMENT SYSTEM, HUBGUARD, TAPE STRIP, 2 ½”X4”
SV254UDT	SORBAVIEW SHIELD SMALL, SECUREMENT SYSTEM, TAPE STRIP, 2 ½”X4”
SV254UDT-6	SORBAVIEW SHIELD SMALL, SECUREMENT SYSTEM, TAPE STRIP, 2 ½”X4”
SV30N2XT	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30N2XT-6	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30NVST	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30NVST-6	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 2 ½”X3”
SV30NXT	SORBAVIEW 2000 WINDOW DRESSING, HUBGUARD, TAPE STRIP, 2 ½”X3”
SV30NXT-6	SORBAVIEW 2000 WINDOW DRESSING, HUBGUARD, TAPE STRIP, 2 ½”X3”
SV30NXT3	SORBAVIEW 2000 WINDOW DRESSING, HUBGUARD, TAPE STRIP, 2 ½”X3”
SV30NXT3-6	SORBAVIEW 2000 WINDOW DRESSING, HUBGUARD, TAPE STRIP, 2 ½”X3”
SV30VST	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30VST-6	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30XT	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV30XT-6	SORBAVIEW 2000 WINDOW DRESSING, 2 ½”X3”
SV353AFXT	SORBAVIEW SHIELD SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP (FOR REMOVAL ONLY), 3 ¾”X5 ½”

SV353AFXT-6	SORBAVIEW SHIELD SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 3 ¾”X5 ½”
SV353UDT	SORBAVIEW SHIELD MEDIUM, SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY), 3 ¾”X5 ½”
SV353UDT-6	SORBAVIEW SHIELD MEDIUM, SECUREMENT SYSTEM, TAPE STRIIP, 3 ¾”X5 ½”
SV353UDTHG	SORBAVIEW SHIELD PLUS PICC, SECUREMENT SYSTEM, HUBGUARD, TAPE STRIP (FOR REMOVAL ONLY), 3 ¾”X5 ½”
SV353UDTHG-6	SORBAVIEW SHIELD PLUS PICC, SECUREMENT SYSTEM, HUBGUARD, TAPE STRIP, 3 ¾”X5 ½”
SV37FL24XT	SORBAVIEW SHIELD EPIDURAL SECUREMENT SYSTEM, TAPE STRIP, 3 ¾”X6 ¼”
SV37FL24XT-6	SORBAVIEW SHIELD EPIDURAL SECUREMENT SYSTEM, TAPE STRIP, 3 ¾”X6 ¼”
SV37UDT	SORBAVIEW SHIELD LARGE, SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY), 3 ¾”X6 ¼”
SV37UDT-6	SORBAVIEW SHIELD LARGE, SECUREMENT SYSTEM, TAPE STRIP, 3 ¾”X6 ¼”
SV40725XT	SORBAVIEW 2000, WINDOW DRESSING, HUBGUARD, 3 ¾”X5”
SV40XT	SORBAVIEW 2000, WINDOW DRESSING, TAPE STRIP, 3 ¾”X5”
SV40XT-6	SORBAVIEW 2000, WINDOW DRESSING, 3 ¾”X5”
SV41AFXT	SORBAVIEW ULTIMATE WINDOW DRESSING WITH ADHESIVE FREE ZONE, 3 ¾”X5 ⅛”
SV41AFXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING WITH ADHESIVE FREE ZONE, 3 ¾”X5 ⅛”
SV41UDXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 3 ¾”X5 ⅛”
SV41UDXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 3 ¾”X5 ⅛”
SV430AFXT	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, 3 ¾”X4 ¾”
SV430AFXT-6	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 3 ¾”X4 ¾”
SV430UDT	SORBAVIEW SHIELD CONTOUR WINDOW DRESSING WITH SHIELD SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY), 3 ¾”X4 ¾”
SV430UDT-6	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM, TAPE STRIP, 3 ¾”X4 ¾”
SV44UDXT	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, TAPE STRIP, 4 ¾”X4 ¼”
SV44UXT	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4”X4 ¼”
SV44UXT-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4”X4 ¼”
SV44UXT2	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4”X4 ¼”
SV44UXT2-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4”X4 ¼”
SV46VST	SORBAVIEW 2000 WINDOW DRESSING, 4”X4”
SV46XT	SORBAVIEW 2000 WINDOW DRESSING, 4”X4”
SV46XT-6	SORBAVIEW 2000 WINDOW DRESSING, 4”X4”
SV48NFST	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 4”X7”
SV48NFST-6	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 3 ¾”X7 ½”
SV48VXT	SORBAVIEW 2000 WINDOW DRESSING, 4”X7”
SV48VXT-6	SORBAVIEW 2000 WINDOW DRESSING, 3 ¾”X7 ½”
SV55XT	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 4 ½”X4 ½”
SV55XT-6	SORBAVIEW 2000 WINDOW DRESSING, 4 ½”X4 ½”
SV60NXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅜”X5 ¾”
SV60NXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅜”X5 ¾”
SV60UXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅜”X5 ¾”
SV60UXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅜”X5 ¾”
SV733AFXT	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, 4 ¾”X6 ¼”
SV733AFXT-6	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 4 ¾”X6”
SV733UDT	SORBAVIEW SHIELD OVAL WINDOW DRESSING WITH SHIELD SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY) 4 ¾”X6”
SV733UDT-6	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM, TAPE STRIP, 4 ¾”X6”
SV80FST	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 5”X6 ½”
SV80XT	SORBAVIEW 2000 WINDOW DRESSING, 5”X6 ½”
SV80XT-6	SORBAVIEW 2000 WINDOW DRESSING, 5”X6 ½”

VSD15ST	VERSADERM 2000 WINDOW DRESSING, TAPE STRIP, 2”X1 ¾”
VSD15ST-6	VERSADERM 2000 WINDOW DRESSING, 2”X1 ¾”
VSD30NST	VERSADERM 2000 WINDOW DRESSING, HUBGUARD, 2 ½”X3”
VSD30NST-6	VERSADERM 2000 WINDOW DRESSING, HUBGUARD, 2 ½”X3”
VSD30ST	VERSADERM 2000 WINDOW DRESSING, 2 ½”X3”
VSD30ST-6	VERSADERM 2000 WINDOW DRESSING, 2 ½”X3”
VAD1683-INT	SURESITE SELECT, 2.75"X 2.875"
VAD1685-INT	SURESITE SELECT, 3.5" X 4.5"
VAD1688-INT	SURESITE SELECT, 4" X 4.5"
VAD1689-INT	SURESITE SELECT, 4" X 6.125"
VAD1680-INT	SURESITE SELECT, 1.55" X1.8"
VAD1682-INT	SURESITE SELECT, 2.25" X2.05"
VAD1882-INT	SURESITE SELECT, 2.8" X3.50"

CENTURION
MEDICAL PRODUCTS

Revision Status

Revision	Issue Date	Revision History	Revised By
0	5/24/2011	• Changed format of entire technical file to allow each part to be revised individually. • Removed reference to 2007 amendment • Added additional product offerings and Authorized Rep. contact info • Removed reference to individual IFU's • Changed format of declaration	J. Helgeson
1	3/16/2012	• Added CMP address • Added Rule • Added additional product codes	J. Helgeson
2	9/24/2012	• Added additional product codes	J. Helgeson
3	04/17/2013	• Added additional product codes • Removed codes no longer CE-marked • Changed format	J. Helgeson
4	04/26/2013	• Added product code SV353AFXT-6	J. Helgeson
5	08/02/2013	• Added product codes SV254DBSXT & SV40725XT • Removed product codes SV353UDT50 & SV37UDT50 • Added "sterile" to Appendix Title	J. Helgeson
6	10/07/2013	• Added product code SV117UDT	A. Reeves
7	01/20/2014	• Revised "description" to match labeling	A. Reeves
8	03/29/2014	• Added product codes SV124XT & SV118UDT	A. Reeves
9	06/19/2014	• Added product codes SV353UDTHG-6 & SV37FL24XT-6	A. Reeves
10	12/22/2014	• Added product code SV15ZXT	A. Reeves
11	04/27/2015	• Added product codes SV577AFXT and SV577UDT	A. Childs
12	06/08/2015	• Added product code SV118UDT-6	A. Childs
13	04/01/2016	• Updated signature format	N. Coan
14	11/08/2016	• Added Annex VII to description.	N. Coan
15	11/15/2016	• Added product codes LVAD66UXT, SCP44VXT, SCP66VXT and SCP66VXT2	A. Childs
16	3/29/2017	• Added product codes LVAD66UXT-6, SCP44VXT-6, SCP66VXT-6, SCP66VXT2-6, SV577AFXT-6, SV577UDT-6	A.Ganton
17	1/11/2019	• Added product code SV233BSXT	A.Ganton
18	3/21/2019	• Removed SIteGuard product codes: SG2300, SG2300-6, SG4500, SG4500-6	A.Ganton

		• Changed BSI UK Notified Body (0086) to NL Notified Body (2797)	
19	7/1/2019	Removed “Appendix 2” from document.	A.Ganton
20	3/27/2020	• Added SureSight product codes: VAD1683, VAD1685, VAD1688, VAD1689, VAD1680, VAD1682, VAD1882	A.Ganton
21	5/20/2020	• Removed MDSS and added Medline France as authorized representative • Revised SureSite product codes to include “INT”	A.Ganton
22	9/25/2020	• Revised DoC for document legalization per EU request. No other changes to DoC.	A.Ganton
23	10/6/2020	• Reverted authorized representative back to MDSS per Quality Bulletin 01-20-005	A.Ganton
24	4/16/2021	• Removed MDSS and added Medline France as authorized representative	A.Ganton
25	10/14/2021	• Removed SV233BSXT, SV577AFXT, SV577AFXT-6, SV577UDT, SV577UDT-6	A.Baughman
26	1/6/2022	• Included statement of amendment • Included SRN for both Centurion and Medline France • Included Basic UDI-DI for devices • Removed SV46VST-6, SV80FST-6, and SV124XT	A.Ganton A.Baughman
27	2/21/2022	• Updated CMP’s name to reflect the name change to Centurion Medical Products, LP	A.Baughman
28	2/22/2022	• Updated to approved format to include required information by BSI for name change and UKCA certificate	A.Baughman