

CE Technical Documentation

Centurion® Sterile Dressing Family

Declaration of Conformity

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 - Changed BSI UK Notified Body (0086) to NL Notified Body (2797)	A.Ganton
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
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Declaration of Conformity Certificate

We, at Centurion Medical Products Corporation, ensure and declare that the medical devices specified in the attached Schedule 1 meet the applicable provisions of Council Directive 93/42/EEC, Annex V and VII certification.

Reference: Schedule 1 attached

Manufacturer's Name: Centurion Medical Products Corporation

Business Address: 100 Centurion Way
Williamston, MI 48895 USA

Medical Device(s): Sterile dressings listed in Schedule 1 attached

Classification: Class I Sterile per Annex IX, Rule 4

Annex V certificate issued by: BSI NL Notified Body (2797)
Certificate No: CE 502193

Authorized Representative Contact Information:

Medline International France SAS
5 Rue Charles Lindbergh
44110 Châteaubriant
France

Signed this 16th day of April, 2021

By: _____

Title: Regulatory Affairs Manager

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"
SV124XT	SORBAVIEW FLEXI C-T INCISION DRESSING WITH ADHESIVE FREE ZONE
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"
SV233BSXT	SORBAVIEW SHIELD PLUS IV, SORBAVIEW SHIELD SECUREMENT SYSTEM, HUBGUARD, TAPE STRIP
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 STRIP, 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 ¾"X4 ¼"
SV44UXT-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 ¾"X4 ¼"
SV44UXT2	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 ¾"X4 ¼"
SV44UXT2-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 ¾"X4 ¼"
SV46VST	SORBAVIEW 2000 WINDOW DRESSING, 4"X4"
SV46VST-6	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"
SV577AFXT	SORBAVIEW SHIELD 577A
SV577AFXT-6	SORBAVIEW SHIELD 577A
SV577UDT	SORBAVIEW SHIELD 577
SV577UDT-6	SORBAVIEW SHIELD 577
SV60NXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅝"X5 ¾"
SV60NXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅝"X5 ¾"
SV60UXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅝"X5 ¾"
SV60UXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 ⅝"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"
SV80FST-6	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"