

Dokumentacja techniczna CE
Centurion® Opatrunki sterylne
Deklaracja zgodności

Status rewizji

Rewizja	Data wydania	Historia zmian	Poprawiony przez
0	5/24/2011	<ul style="list-style-type: none"> Zmieniono format całej dokumentacji technicznej, aby umożliwić każdemu część do indywidualnego przeglądu. Usunięto odniesienie do poprawki z 2007 r. Dodano dodatkowe oferty produktów i autoryzowanego przedstawiciela. informacje kontaktowe Usunięto odniesienie do poszczególnych IFU Zmieniony format deklaracji 	J. Helgeson
1	3/16/2012	<ul style="list-style-type: none"> Dodano adres CMP Dodano regulę Dodano dodatkowy kod produktu 	J. Helgeson
2	9/24/2012	Dodano dodatkowe kody produktów	J. Helgeson
3	04/17/2013	<ul style="list-style-type: none"> Dodano dodatkowe kody produktów Usunięte kody nie mają już znaku CE Zmieniony format 	J. Helgeson
4	04/26/2013	Dodano kod produktu SV353AFXT-6	J. Helgeson
5	08/02/2013	<ul style="list-style-type: none"> Dodano kody produktów SV254DBSXT i SV40725XT Usunięto kody produktów SV353UDT50 i SV37UDT50 Dodano „sterylny” do tytułu dodatku 	J. Helgeson
6	10/07/2013	Dodano kod produktu SV117UDT	A. Reeves
7	01/20/2014	<ul style="list-style-type: none"> Revised “description” to match labeling 	A. Reeves
8	03/29/2014	<ul style="list-style-type: none"> Dodano kody produktów SV124XT & SV118UDT 	A. Reeves
9	06/19/2014	<ul style="list-style-type: none"> Dodano kody produktów SV353UDTHG-6 & SV37FL24XT-6 	A. Reeves
10	12/22/2014	Dodano kod produktu SV15ZXT	A. Reeves
11	04/27/2015	<ul style="list-style-type: none"> Dodano kody produktów SV577AFXT and SV577UDT 	A. Childs
12	06/08/2015	Dodano kod produktu SV118UDT-6	A. Childs
13	04/01/2016	Zaktualizowany format podpisu	N. Coan
14	11/08/2016	Dodano Aneks VII do opisu.	N. Coan
15	11/15/2016	<ul style="list-style-type: none"> Dodano kody produktów LVAD66UXT, SCP44VXT, SCP66VXT i SCP66VXT2 	A. Childs
16	3/29/2017	<ul style="list-style-type: none"> Dodano kody produktów LVAD66UXT-6, SCP44VXT-6, SCP66VXT-6, SCP66VXT2-6, SV577AFXT-6, SV577UDT-6 	A.Ganton
17	1/11/2019	Dodano kod produktu SV233BSXT	A.Ganton
18	3/21/2019	<ul style="list-style-type: none"> Usunięto kody produktów SiteGuard: SG2300, SG2300-6, SG4500, SG4500-6 Zmieniono jednostkę notyfikowaną BSI UK (0086) na jednostkę notyfikowaną NL (2797) 	A.Ganton
19	7/1/2019	Usunięto „Dodatek 2” z dokumentu.	A.Ganton
20	3/27/2020	<ul style="list-style-type: none"> Dodano kody produktów SureSight: VAD1683, VAD1685, VAD1688, VAD1689, VAD1680, VAD1682, VAD1882 	A.Ganton
21	5/20/2020	<ul style="list-style-type: none"> Usunięto MDSS i dodano Medline France jako autoryzowanego przedstawiciela Zmienione kody produktów SureSite w celu uwzględnienia „INT” 	A.Ganton

Deklaracja Certyfikatu Zgodności

My, w Centurion Medical Products Corporation, zapewniamy i deklarujemy, że wyroby medyczne określone w załączonym Załączniku 1 są zgodne z obowiązującymi przepisami dyrektywy Rady 93/42/EWG, aneks V i VII certyfikacji.

Odniesienie: Aneks 1 w załączeniu

Nazwa producenta: Centurion Medical Products Corporation

Adres firmy: 100 Centurion Way
Williamston, MI 48895 USA

Wyrób(-a) Opatrunki sterylne wymienione w Aneksie 1

medyczne: załączonym

Klasyfikacja: Klasa I Sterylne zgodnie z Aneksem IX, Reguła

4

Certyfikat Aneksu V wydany przez: Jednostkę
Notyfikowaną BSI NL (2797)
Certyfikat nr: CE 502193

Informacje kontaktowe autoryzowanego przedstawiciela:
Medline International France SAS
5 Rue Charles Lindbergh
44110 Châteaubriant
France

_____ Podpisano 12 Lipca, 2020 _____

Przez Podpis nieczytelny

Tytuł: Kierownik ds. Regulacji

Aneks 1 do Deklaracji Zgodności

Nr komponentu	Opis obiektu
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 3/4"X5 1/2"
SV37FL24XT	SORBAVIEW SHIELD EPIDURAL SECUREMENT SYSTEM, TAPE STRIP, 3 3/4"X6 1/4"
SV37FL24XT-6	SORBAVIEW SHIELD EPIDURAL SECUREMENT SYSTEM, TAPE STRIP, 3 3/4"X6 1/4"
SV37UDT	SORBAVIEW SHIELD LARGE, SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY), 3 3/4"X6 1/4"
SV37UDT-6	SORBAVIEW SHIELD LARGE, SECUREMENT SYSTEM, TAPE STRIP, 3 3/4"X6 1/4"
SV40725XT	SORBAVIEW 2000, WINDOW DRESSING, HUBGUARD, 3 3/4"X5"
SV40XT	SORBAVIEW 2000, WINDOW DRESSING, TAPE STRIP, 3 3/4"X5"
SV40XT-6	SORBAVIEW 2000, WINDOW DRESSING, 3 3/4"X5"
SV41AFXT	SORBAVIEW ULTIMATE WINDOW DRESSING WITH ADHESIVE FREE ZONE, 3 3/4"X5 1/8"
SV41AFXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING WITH ADHESIVE FREE ZONE, 3 3/4"X5 1/8"
SV41UDXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 3 3/4"X5 1/8"
SV41UDXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 3 3/4"X5 1/8"
SV430AFXT	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, 3 3/4"X4 3/4"
SV430AFXT-6	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 3 3/4"X4 3/4"
SV430UDT	SORBAVIEW SHIELD CONTOUR WINDOW DRESSING WITH SHIELD SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY), 3 3/4"X4 3/4"
SV430UDT-6	SORBAVIEW SHIELD CONTOUR SECUREMENT SYSTEM, TAPE STRIP, 3 3/4"X4 3/4"
SV44UDXT	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, TAPE STRIP, 4 3/4"X4 1/4"
SV44UXT	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4"X4 1/4"
SV44UXT-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4"X4 1/4"
SV44UXT2	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4"X4 1/4"
SV44UXT2-6	SORBAVIEW ULTIMATE IJ WINDOW DRESSING, 4 3/4"X4 1/4"
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 3/4"X7 1/2"
SV48VXT	SORBAVIEW 2000 WINDOW DRESSING, 4"X7"
SV48VXT-6	SORBAVIEW 2000 WINDOW DRESSING, 3 3/4"X7 1/2"
SV55XT	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 4 1/2"X4 1/2"
SV55XT-6	SORBAVIEW 2000 WINDOW DRESSING, 4 1/2"X4 1/2"
SV577AFXT	SORBAVIEW SHIELD 577A
SV577AFXT-6	SORBAVIEW SHIELD 577A
SV577UDT	SORBAVIEW SHIELD 577
SV577UDT-6	SORBAVIEW SHIELD 577
SV60NXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 3/8"X5 3/4"
SV60NXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 3/8"X5 3/4"
SV60UXT	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 3/8"X5 3/4"
SV60UXT-6	SORBAVIEW ULTIMATE WINDOW DRESSING, 4 3/8"X5 3/4"
SV733AFXT	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, 4 3/4"X6 1/4"
SV733AFXT-6	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM WITH ADHESIVE FREE ZONE, TAPE STRIP, 4 3/4"X6"
SV733UDT	SORBAVIEW SHIELD OVAL WINDOW DRESSING WITH SHIELD SECUREMENT SYSTEM, TAPE STRIP (FOR REMOVAL ONLY) 4 3/4"X6"
SV733UDT-6	SORBAVIEW SHIELD OVAL SECUREMENT SYSTEM, TAPE STRIP, 4 3/4"X6"
SV80FST	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 5"X6 1/2"
SV80FST-6	SORBAVIEW 2000 WINDOW DRESSING, TAPE STRIP, 5"X6 1/2"
SV80XT	SORBAVIEW 2000 WINDOW DRESSING, 5"X6 1/2"
SV80XT-6	SORBAVIEW 2000 WINDOW DRESSING, 5"X6 1/2"
VSD15ST	VERSADERM 2000 WINDOW DRESSING, TAPE STRIP, 2"X1 3/4"
VSD15ST-6	VERSADERM 2000 WINDOW DRESSING, 2"X1 3/4"
VSD30NST	VERSADERM 2000 WINDOW DRESSING, HUBGUARD, 2 1/2"X3"
VSD30NST-6	VERSADERM 2000 WINDOW DRESSING, HUBGUARD, 2 1/2"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"

CE Technical Documentation

Centurion® Sterile Dressing Family

Declaration of Conformity

Revision Status

Revision	Issue Date	Revision History	Revised By
0	5/24/2011	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Added CMP address Added Rule Added additional product codes 	J. Helgeson
2	9/24/2012	<ul style="list-style-type: none"> Added additional product codes 	J. Helgeson
3	04/17/2013	<ul style="list-style-type: none"> Added additional product codes Removed codes no longer CE-marked Changed format 	J. Helgeson
4	04/26/2013	<ul style="list-style-type: none"> Added product code SV353AFXT-6 	J. Helgeson
5	08/02/2013	<ul style="list-style-type: none"> Added product codes SV254DBSXT & SV40725XT Removed product codes SV353UDT50 & SV37UDT50 Added "sterile" to Appendix Title 	J. Helgeson
6	10/07/2013	<ul style="list-style-type: none"> Added product code SV117UDT 	A. Reeves
7	01/20/2014	<ul style="list-style-type: none"> Revised "description" to match labeling 	A. Reeves
8	03/29/2014	<ul style="list-style-type: none"> Added product codes SV124XT & SV118UDT 	A. Reeves
9	06/19/2014	<ul style="list-style-type: none"> Added product codes SV353UDTHG-6 & SV37FL24XT-6 	A. Reeves
10	12/22/2014	<ul style="list-style-type: none"> Added product code SV15ZXT 	A. Reeves
11	04/27/2015	<ul style="list-style-type: none"> Added product codes SV577AFXT and SV577UDT 	A. Childs
12	06/08/2015	<ul style="list-style-type: none"> Added product code SV118UDT-6 	A. Childs
13	04/01/2016	<ul style="list-style-type: none"> Updated signature format 	N. Coan
14	11/08/2016	<ul style="list-style-type: none"> Added Annex VII to description. 	N. Coan
15	11/15/2016	<ul style="list-style-type: none"> Added product codes LVAD66UXT, SCP44VXT, SCP66VXT and SCP66VXT2 	A. Childs
16	3/29/2017	<ul style="list-style-type: none"> Added product codes LVAD66UXT-6, SCP44VXT-6, SCP66VXT-6, SCP66VXT2-6, SV577AFXT-6, SV577UDT-6 	A.Ganton
17	1/11/2019	<ul style="list-style-type: none"> Added product code SV233BSXT 	A.Ganton
18	3/21/2019	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Added SureSight product codes: VAD1683, VAD1685, VAD1688, VAD1689, VAD1680, VAD1682, VAD1882 	A.Ganton
21	5/20/2020	<ul style="list-style-type: none"> Removed MDSS and added Medline France as authorized representative Revised SureSite product codes to include "INT" 	A.Ganton

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 12th day of July, 2020

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"

Certyfikat CE - Zapewnienie Jakości Produkcji

Dyrektywa 93/42/EWG w sprawie wyrobów medycznych, aneks V

Nr.

CE 502193

Wystawiony dla:

**Centurion Medical Products Corporation
100 Centurion Way
Williamston
Michigan
48895
USA**

W odniesieniu do:

Aspekty Aneksu V odnoszące się do zabezpieczania i utrzymywania sterylności tlenkiem etylenu w produkcji sterylnych opatrunków i urządzeń mocujących.

na podstawie naszego badania systemu zapewniania jakości zgodnie z wymaganiami Dyrektywy Rady 93/42/EWG, aneks V. System zapewnienia jakości spełnia wymagania dyrektywy.

Do wprowadzenia do obrotu wyrobów klasy IIb i klasy III wymagane jest świadectwo z aneksu III.

W imieniu i na rzecz BSI, jednostka notyfikowana dla powyższej dyrektywy (numer jednostki notyfikowanej 2797):

Podpis nieczytelny

Gary E Slack, starszy wiceprezes ds. urządzeń medycznych**Pierwsze wydanie: 2006-03-24****Data: 2021-01-20****Data ważności: 2024-05-26**

...making excellence a habit.™

Str 1 z 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certyfikat EC - Zapewnienie Jakości Produkcji

Informacje uzupełniające do CE 502193

Wystawiony dla:

Centurion Medical Products Corporation
100 Centurion Way
Williamston
Michigan
48895
USA

Kod(y) NBOG	Opis produktu	Zamierzony cel
Klasa I sterylna		
MD 0301	Sterylnie opatrunki Opatrunki do dostępu naczyniowego / urządzenia zabezpieczające	N/D dla wyrobów sterylnych klasy I

Pierwsze wydanie: **2006-03-24**Data: **2021-01-20**Data ważności: **2024-05-26**

...making excellence a habit.™

Str 2 z 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 502193****Issued To:**

**Centurion Medical Products Corporation
100 Centurion Way
Williamston
Michigan
48895
USA**

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility by ethylene oxide in the manufacture of sterile dressings and securement devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-03-24**

Date: **2021-01-20**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 502193

Issued To:

Centurion Medical Products Corporation
100 Centurion Way
Williamston
Michigan
48895
USA

NBOG code(s)	Device description	Intended purpose
Class I Sterile		
MD 0301	Sterile Dressings Vascular Access Dressings / Securement Devices	NA for Class I Sterile devices

First Issued: **2006-03-24**Date: **2021-01-20**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.