

<b>Manufacturer:</b>	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss The Netherlands Phone: +31 (0) 412 667 755 Email: info@sterisets.com www.sterisets.com
<b>SRN:</b>	NL-MF-000030883
<b>Product category:</b>	Wrappers & drapes
<b>Product families:</b>	
<u>Designation:</u>	<u>Intended purpose:</u>
Surgical drapes	For draping of patients and wrapping of medical devices to prevent transfer of infective agents
Wrapping fields	When sterile, intended to be used for sterile draping of patients and medical devices in O.R. to prevent transfer of infective agents
Bibs	
Drapes	
Drawsheets	
<b>Risk classification:</b>	Class I
<b>Rule:</b>	1
<b>Conformity assessment route:</b>	Annex II and III
<b>Common specifications:</b>	Not applicable
<b>ISO 9001 certificate no.:</b>	2156451
<b>Certification company:</b>	DEKRA Certification B.V.

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of Sterisets International B.V. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

**Signature:**  
**Name:** Joana Pereira  
**Function:** Management representative  
**Place and Date:** Oss 20-11-2023

To DoC number: DoC2156451TDC4

The medical devices which fall under the DoC are:

**Product category:** Wrappers & drapes

**Product family:** Surgical drapes

**Basic UDI-DI:** 872059888SURGDRAF23CS

REF	Designation
95052	Drape jaw SMS 90x160cm with abs.field fen 10x20cm impermeabl
95054	Drape jaw 2 ply 90 x 150 cm blue folded
95055	Drape top reinf. 240x150cm with 2 layer lami. adhes+velcro
95051	Drape jaw PE/NW 2 ply 100 x 100 cm split 20 x 15 cm adh blue
95060	Drape top 2 ply 150 x 260 cm
95061	Drape top 270 x 150 cm with armboard cover
95062	Drape side 100 x 112 cm with adhesive
95065	Drape bottom 2 ply 180 x 196 cm
95066	Drape bottom pediatric 175 x 180 cm with 80 x 2.5cm adhesive
95067	Drape bottom 2 ply 180 x 196 cm with adhesive 120cm
95068	Drape bottom reinf. 150x180cm, 2 layer lamin. w/ adhesi+velc
95069	Drape Ophthalmic 150x105cm, with 2 fluid ,collection pouch
95070	Drape sheet 100 x 150 cm
95071	Drape sheet 100 x 170 cm with 100 X 5 cm adhesive
95072	Drape 100 x 150 cm with adhesive
95074	Drape sheet 180 x 150 cm
95080	Drape sheet 150 x 250 cm, with 85 x 5 cm adhesive
95085	Drape sheet 180 x 180 cm, with 85x 5 cm adhesive
95220	Cover foot 16,55 x 37 cm
95302	Drape lateral fenestration 2 ply 75 x 90 cm Ø 10 cm w. adh.
95303	Drape lateral fenestration 2 ply 150 x 220 cm Ø10 cm w. adh.
95304	Drape lateral fenestration 2 ply 130 x 250 cm Ø10 cm w. adh.
95305	Drape eye SMS 45 gr/m2 40 x 40 cm incise 11,5x9 cm split 5cm
95307	Drape fen. 2 ply 100 x 150 cm Ø 10 x 10 cm w adhesive
95312	Eye drape 40 x 40 cm, 45 g/m2 blue anti-static SMS non woven, oval
95440	Drape eye 2 ply 140 x 150 cm 1 x pouch/incise hole 8 x 10 cm
95442	Drape eye spunlaced 110 x 155 cm fen. 6 x 8 cm w. adh.
95443	Drape eye SMS 45 gr/m2 180 x 160 cm incise/2 x pouch
95444	Drape eye 2 ply 140 x 150 cm incise 1 x pouch fen. 6 x 18 cm
95447	Drape eye SMS 45 gr/m2 220 x 160 cm incise/2 x pouch fen 15c
95451	Drape eye SMMS 45 gr/m2 53 x 75 cm 1 pouch/ fen. 11,5 x 9 cm
95453	Eye Drape 140x150 cm two pouches Fenestration 8x10
95501	Drape angio 230 x 300 cm universal with 2 instr. panels
95502	Drape angio 230 x 350 cm 4 windows Ø 9/4x6 cm
95503	Drape pacemaker 228 x 330 cm 2 windows Ø 2,25 x 6 cm
95504	Drape angio 220 x 330 cm instrument pannel full right side
95505	Drape angio femoral 230 x 310 cm 2 windows Ø 15x17cm qw bag
95506	Drape angio special XL 220x330cm 2 fen 2 part. instr. pannel
95507	Drape Angio 2 ply 3 fen. 230 x 260 cm extra incision foil
95510	Drape hip 300 x 200 x 350 cm flex opening and pouches

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**Product family:** Surgical drapes

**Basic UDI-DI:** 872059888SURGDRAF23CS

REF	Designation
95514	Drape angio 230 x 350 cm 4 windows Ø 9/4x6 cm centric 2xPE
95515	Drape Pacemaker 2x incise fen. bags both on sides 230x340cm
95530	Drape vertical isolation 240 x 330 cm incise 90 x 32 cm
95531	Drape vertical isolation 240 x 320 cm incise 22 x 57 cm
95533	Drape vert.isolation 240x320cm small incise 24x47cm no pouch
95540	Drape 90 x 110 cm PE transparent folded, with adhesive
95560	Drape arthroscopy 230 x 310 cm with pouch
95562	Drape arthroscopy 230x310cm flexible fenestr. 6cm w/pouch
95565	Drape split shoulder 230 x 260 cm w. fluid control pouch
95575	Drape extremity 230 x 330 cm flexible fenestration 7cm
95576	Drape extremity 230 x 330 cm fenestration with T
95578	Drape extremity 230 x 330 cm flexible fenestration 6cm
95580	Drape hand 150/354 x 297 cm aperture size 3 cm
95585	Drape hand 150/370 x 310 cm aperture 3 cm absorb. 42 x 85 cm
95600	Drape craniotomy 228 x 320 cm incise/pouch
95602	Drape Elekta Steriotactic PE 215 x 240 cm
95606	Drape laparoscopic lithotomie pos. 260/230 x241cm Ø 26x30 cm
95640	Drape TUR mesh screen 260/150 x 240 cm att. leggings
95641	Drape TUR 155/255 x 162 cm w. fluid contr. pouch/finger cot
95651	Drape C-section 200/250 x 286 cm w. fenestration in T-shape
95652	Drape C-section 180/250 x 300 cm with incise pouch with wire
95653	Drape gynaecology 260/304 cm Ø 10 x 12 cm with adhesive
95654	Drape gynaecology 200/260 x 177 cm
95655	Drape CV Incision 200 x 360 cm
95656	Drape gynaecological fenestrated
95658	Drape breast cover 250/190 x 325 cm
95670	Drape thyroid 200 x 310 cm
95682	Drape gynaecology 150x190x75cm w/ fen reinforced
95690	Drape CV perineal 200 x 250 cm
95691	Drape perineal 200 x 250 cm fen. 40 x 45 cm w. inc. foil
95700	Drape PE 205 x 150 cm split 80 cm
95701	Drape split PE 265 x 150 cm split 80 cm
95705	Drape split large 200 x 280 cm split 23 x 76 cm
95710	Drape split 270 x 230 cm split 15 x 102 cm
95714	Drape Split 150x250cm, split 7x70cm
95715	Drape ENT split 200 x 280 cm split 65 cm
95720	Drape split 230 x 260 cm split 100X20 cm adhesive
95740	Drape fenestrated ENT 220 x 230 cm hole 5 x 6 cm
95745	Drape turban head 100 x 70 cm
95800	Drape TUR SMS with mesh screen and condom

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**Product family:** Surgical drapes

**Basic UDI-DI:** 872059888SURGDRAF23CS

REF	Designation
95802	Drape pediatric 200 x 280 cm Ø 10 cm w. adhesive
95805	Drape fenestrated 120 x 150 cm hole 7 x 5 cm w/adhesive
95809	Drape 2 ply 112 x 150 cm, 60 g/m2 hole 10 x 15 cm PE/NW folded
95812	Drape circumcise 75 x 115 cm with fenestration Ø 2 cm
95835	Arm cover 2 ply 38 x 75 cm
95837	Cover arm rest 20/60 x 75 cm
95640-1	Drape TUR mesh screen 260/150 x 240 cm att. leggings
95996	Drape under buttock 120x100 cm with pouch

**Product category:** Wrappers & drapes

**Product family:** Wrapping fields

**Basic UDI-DI:** 872059888WRAPFIELF314X

REF	Designation
1001	Wrapping field PE/Tissue 38 x 41 cm green
1002	Wrapping field PE/Tissue 38 x 43 cm blue
1003	Wrapping field PE/Tissue 50 x 50 cm green
1004	Wrapping field PE/Tissue 50 x 70 cm blue
1006	Wrapping field PE/Tissue 70 x 50 cm green
1007	Wrapping field PE/Tissue 50 x 70 cm blue
1009	Wrapping field PE/Tissue 70 x 60 cm green
1010	Wrapping field PE/Tissue 70 x 60 cm green
1013	Wrapping field PE/Tissue 70 x 90 cm green
1014	Doek 2 laags PE tissue niet gevouwen
1015	Wrapping field PE/Tissue 70 x 90 cm blue
3201	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 50 x 70 cm blue
3202	Wrapping field 2 ply PE 33 gr/m2 NW 30gr/m2 75 x 75 cm blue
3203	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 75 x 90 cm blue
3204	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 90 x 90 cm blue
3207	Wrapping field 2 ply PE 25gr/m2 NW 30 gr/m2 90 x 150 cm blue
641050	Wrapping field SMS 40 gram 50 x 50 cm blue
641060	Wrapping field SMS 40 gram 60 x 60 cm blue
641075	Wrapping field SMS 40 gram 75 x 75 cm blue
641090	Wrapping field SMS 40 gram 90 x 90 cm blue
641100	Wrapping field SMS 40 gram 100 x 100 cm blue
641120	Wrapping field SMS 40 gram 120 x 120 cm blue

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The medical devices which fall under the DoC are:

**Product category:** Wrappers & drapes

**Product family:** Bibs

**Basic UDI-DI:** 872059888BIBSSSSSF33UA

REF	Designation
1000	Bib dental 38 x 30 cm

**Product category:** Wrappers & drapes

**Product family:** Drapes

**Basic UDI-DI:** 872059888DRAPESSSF8YB

REF	Designation
1100	Drape PE/Tissue 38 x 43 cm blue
1101	Drape PE/Tissue 38 x 43 cm green
1102	Drape 2 ply 38 x 46 cm, PE tissue folded
1103	Drape PE/Tissue 38 x 43 cm green
1104	Drape 2 ply 55 x 60 cm, PE tissue folded
1105	Drape 2 ply 50 x 50 cm green
1107	Drape PE/Tissue 50 x 60 cm green
1111	Drape PE/Tissue 50 x 80 cm outside folded green
1112	Drape PE/Tissue 70 x 50 cm green
1113	Drape PE/Tissue 70 x 90 cm green
1115	Drape 2 ply 70 x 90 cm, PE tissue folded
1120	Drape PE/Tissue 45 x 75 cm green
1140	Drape 2 ply 55 x 60 cm, PE tissue, hole $\phi$ 5 cm, slit, folded
1141	Drape PE/Tissue 50 x 50 cm with fen. $\phi$ 9 cm green
1144	Drape PE/Tissue 50 x 80 cm with fen. $\phi$ 10 cm green
1145	Drape PE/Tissue 50 x 80 cm with fen. $\phi$ 6 cm & split green
1146	Drape PE/Tissue 50 x 80 cm with fen. $\phi$ 6 cm green
1147	Drape PE/Tissue 50x80cm w. fen. diamond $\phi$ 8,5cm & split green
1148	Drape PE/Tissue 50 x 50 cm with fen. $\phi$ 6 cm green
1149	Drape PE/Tissue 50 x 80 cm with split green
1150	Drape PE/Tissue 55 x 60 cm with fen. $\phi$ 6 cm + 4 adh. corners
1151	Drape PE/Tissue 70 x 90 cm with fen. $\phi$ 6 cm green
3205	Drape 2 ply 75 x 110 cm, 60 g/m2 PE/NW not folded
3206	Drape 2 ply 100 x 100 cm, 60 g/m2 PE/NW not folded
3210	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 40x60cm
3211	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 50x70cm
3213	Drape 2 ply 70 x 90 cm, 60 g/m2 PE/NW folded
3214	Drape 3 ply 90 x 90 cm, 54 g/m2 T/PE/NW folded
3215	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 40x45 cm

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The medical devices which fall under the DoC are:

**Product category:** Wrappers & drapes

**Product family:** Drapes

**Basic UDI-DI:** 872059888DRAPESSF8YB

REF	Designation
3217	Drape 2 ply 90 x 150 cm, 60 g/m2 PE/NW folded
3223	Drape 2 ply PE 27 gr/m2 NW 28 gr/m2 60x60cm Lateral Adhesive
3224	Drape 2 ply 70 x 90 cm, PE/NW folded, with adhesive
3225	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 75x75cm lateral adhesive
3228	Drape 2 ply 50 x 60 cm , w. Adh. Around fen.Ø 6,5 cm blue
3229	Drape 2 ply 60 x 50 cm w. adh. around fen. 6 x 8 cm blue
3230	Drape 2 ply 75 x 90 cm w. adh. around fen. 6 x 8 cm blue
3231	Drape PE transparent 75x90cm fen. Ø 10cm+adh. & lateral adh.
3232	Drape 3 ply 70 x 50 cm, 54 g/m2 hole Ø 7 cm T/PE/NW folded
3233	Drape 2 ply 70 x 90 cm fen. Ø 6 cm
3234	Drape 3 ply 70 x 90 cm, 54 g/m2 hole Ø 10 cm T/PE/NW folded
3235	Drape 2 ply 75 x 90 cm fen. Ø 15 x 6 cm w. adh.
3236	Drape 2 ply 75 x 90 cm fen. Ø 10cm w. adh. blue
3237	Drape 2 ply 70 x 90 cm, 60 g/m2 hole Ø 12 cm PE/NW folded, with adhesive
3238	Drape 3 ply 70 x 90 cm, 54 g/m2 hole Ø 10 x 12 cm T/PE/NW folded, with adhesive
3239	Drape 2 ply PE/NW 90 x 150 cm Ø 10 cm
3240	Drape 2 ply 45 x 75 cm w. adh. around split 18 x 15 cm blue
3241	Drape 2 ply 75 x 90 cm w. adh. around split 6 x 10 cm blue
3244	Drape 2 ply 75x75cm PE 35x35cm w adh around fen. Ø10cm
3247	Drape 2 ply 75 x 90cm adh around fen Ø 10x15cm adh corn blue
3248	Drape 2 ply plastic 41 x 20 cm w. fen. 7,5 x 2,5 cm
3256	Drape 2 ply 70 x 90 cm fen. Ø 10 cm, with split
3266	Drape PE 75 x 90 cm fen. Ø 10 cm transparent
3267	Drape PE 75 x 90 cm fen. Ø 15 cm transparent
640075	Drape SMS 75 x 75 cm folded
640090	Drape SMS 90 x 90 cm blue folded
703903006	Folded field 60 x 60 cm 38 g / m2
703903007	Folded field 50 x 50 cm, with hole and cut 38 g / m2

To DoC number: DoC2156451TDC4

The medical devices which fall under the DoC are:

**Product category:** Wrappers & drapes

**Product family:** Drawsheets

**Basic UDI-DI:** 872059888DRAWSHEEF9YR

REF	Designation
1052	Drawsheets 210 x 80 cm transparent
1054	Drawsheet 210 x 80 cm with 50 threads
1073	Draglakan 140 x 80 cm, 44gr/m2
1078	Draglakan 150 x 80 cm 44 g / m2
1080	Drawsheets 170 x 80 cm, 47g / m2
1082	Drawsheet 170 x 80 cm with 50 threads
1087	Drawsheet 190 x 80 cm with 50 threads

**Signature:**

**Name:**

Joana Pereira

**Function:**

Management representative

**Place and Date:**

Oss 20-11-2023