

Manufacturer:	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss The Netherlands Phone: +31 (0) 412 667 755 Email: info@sterisets.com www.sterisets.com
SRN:	NL-MF-000030883
Product category:	Medical equipment covers
Product families:	
<u>Designation:</u>	<u>Intended purpose:</u>
Medical equipment covers Table covers	For draping of medical equipment to prevent transfer of infective agents When sterile, intended to be used for sterile draping of theatre equipment in O.R. to prevent transfer of infective agents
Risk classification:	Class I
Rule:	1
Conformity assessment route:	Annex II and III
Common specifications:	Not applicable
ISO 9001 certificate no.:	2156451
Certification company:	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: DoC2156451TDC7

The medical devices which fall under the DoC are:

Product category: Medical equipment covers

Product family: Medical equipment covers

Basic UDI-DI: 872059888MEDEQUCOF16MT

REF	Designation
3700	Drill cover SMS 120 x 12,5 cm 45 g without cord
3701	Drill cover SMS 110 x 9 cm with cord
3704	Drill cover SMS 120 X 17 cm 45 g with adhesive strip
95532	Isolation bag PE 53 x 52 cm
95900	Drape camera PE 15 x 250 cm comfort
95912	Light handle cover universal, green, Ø 5,2 cm, w/ PP ring
95929	Light handle cover, diameter 12cm
95950	Dome bag 35 x 70 cm PE
95954	Dome bag PE 50 x 100 cm
95955	Dome bag 60 x 120 cm PE
95956	Banded bag 130 x 70 cm PE
95958	Dome bag 150 cm round PE
95980	Pouch diathermy 33 x 41 cm 2 compartments
95981	Pouch diathermy 33 x 40 cm 1 compartment
95985	Casette cover 60 x 60 cm with adhesive
95987	Pouch instrument long 24,5 x 47 cm 3 compartments double adh
95995	Pouch fluid collection 49 x 60 cm adh.alu strip+filter+drain

To DoC number: DoC2156451TDC7

The medical devices which fall under the DoC are:

Product category: Medical equipment covers

Product family: Table covers

Basic UDI-DI: 872059888TABLECOVF27KT

REF	Designation
95101	Cover table PE 100 x 150 cm non folded
95102	Cover table PE 100 x 110 cm non folded
95103	Cover table PE 150 x 195 cm folded
95104	Cover table PE 112 x 188 cm non folded
95105	Cover table PE 150 x 190 cm non folded
95106	Cover table PE 140 x 216 cm non folded
95108	Cover table PE 150 x 230 cm heavy duty soft folded
95110	Cover table PE 200 x 230 cm folded
95112	Cover table PE 200 x 230 cm non folded
95113	Cover table PE 140 x 190 cm folded special reinf.
95114	Cover table PE 140 x 190 cm non folded special reinf
95150	Cover Mayo stand 79 x 145 cm
95151	Cover Mayo stand 79 x 145 cm special reinf.
95155	Cover Mayo stand HD 79 x 145 cm
95160	Cover Mayo stand XL SMS reinforcement 120 x 170 cm

Signature:

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