

**Manufacturer:** Sterisets International B.V.  
Ketelmeer 3 – 5347 JX Oss, The Netherlands  
Tel: +31 412 667 755 Email info@sterisets.com  
www.sterisets.com

**Medical devices:**

**Designation:** Medical equipment covers  
Table covers

**Intended purpose:** When sterile, intended to be used for sterile draping of theatre equipment in O.R. to prevent transfer of infective agents

**Risk Class:** According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.  
Class I

**Rule:** 1

**Conformity assessment route:** Annex IX

**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:** Jos van der Kwartel

**Function:** Management representative

**Place and Date:**

To DoC number: DoC2156451-7 The medical devices which fall under the DoC are:

Product category: **Medical equipment covers, Table covers**

REF	Designation	Basic UDI-DI	Trade name
3700	Drill cover SMS 120 x 12,5 cm 45 g without cord	872059888MEDEQUCOF16MT	medisp
3701	Drill cover SMS 110 x 9 cm with cord	872059888MEDEQUCOF16MT	medisp
3704	Drill cover SMS 120 X 17 cm 45 g with adhesive strip	872059888MEDEQUCOF16MT	medisp
95101	Cover table PE 100 x 150 cm non folded	872059888TABLECOVF27KT	medisp
95102	Cover table PE 100 x 110 cm non folded	872059888TABLECOVF27KT	medisp
95103	Cover table PE 150 x 195 cm folded	872059888TABLECOVF27KT	medisp
95104	Cover table PE 112 x 188 cm non folded	872059888TABLECOVF27KT	medisp
95105	Cover table PE 150 x 190 cm non folded	872059888TABLECOVF27KT	medisp
95106	Cover table PE 140 x 216 cm non folded	872059888TABLECOVF27KT	medisp
95108	Cover table PE 150 x 230 cm heavy duty soft folded	872059888TABLECOVF27KT	medisp
95110	Cover table PE 200 x 230 cm folded	872059888TABLECOVF27KT	medisp
95112	Cover table PE 200 x 230 cm non folded	872059888TABLECOVF27KT	medisp
95113	Cover table PE 140 x 190 cm folded special reinf.	872059888TABLECOVF27KT	medisp
95114	Cover table PE 140 x 190 cm non folded special reinf	872059888TABLECOVF27KT	medisp
95150	Cover Mayo stand 79 x 145 cm	872059888TABLECOVF27KT	medisp
95151	Cover Mayo stand 79 x 145 cm special reinf.	872059888TABLECOVF27KT	medisp
95155	Cover Mayo stand HD 79 x 145 cm	872059888TABLECOVF27KT	medisp
95160	Cover Mayo stand XL SMS reinforcement 120 x 170 cm	872059888TABLECOVF27KT	medisp
95532	Isolation bag PE 53 x 52 cm	872059888MEDEQUCOF16MT	medisp
95900	Drape camera PE 15 x 250 cm comfort	872059888MEDEQUCOF16MT	medisp
95912	Light handle cover universal	872059888MEDEQUCOF16MT	medisp
95929	Light handle cover, diameter 12cm	872059888MEDEQUCOF16MT	medisp
95950	Dome bag 35 x 70 cm PE	872059888MEDEQUCOF16MT	medisp
95954	Dome bag PE 50 x 100 cm	872059888MEDEQUCOF16MT	medisp
95955	Dome bag 60 x 120 cm PE	872059888MEDEQUCOF16MT	medisp
95956	Banded bag 130 x 70 cm PE	872059888MEDEQUCOF16MT	medisp
95958	Dome bag 150 cm round PE	872059888MEDEQUCOF16MT	medisp
95980	Pouch diathermy 33 x 41 cm 2 compartments	872059888MEDEQUCOF16MT	medisp
95981	Pouch diathermy 33 x 40 cm 1 compartment	872059888MEDEQUCOF16MT	medisp
95985	Casette cover 60 x 60 cm with adhesive	872059888MEDEQUCOF16MT	medisp
95987	Pouch instrument long 24,5 x 47 cm 3 compartments double adh	872059888MEDEQUCOF16MT	medisp
95995	Pouch fluid collection 49 x 60 cm adh.alu strip+filter+drain	872059888MEDEQUCOF16MT	medisp

**Signature:**

**Name:** Jos van der Kwartel  
**Function:** Management representative

**Place and Date:**