

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:	Personal protection equipment
Product families:	
<u>Designation:</u>	<u>Intended purpose:</u>
Examination gloves Isolation gowns Mobcaps Shoe covers Surgical gowns Face masks Hand towels	To use in the medical field to protect patient and user for cross-contamination
Risk classification:	Class I
Rule:	1 & 5
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: DoC2156451TDC3

The medical devices which fall under the DoC are:

Product category: Personal protection equipment

Product family: Examination gloves

Basic UDI-DI: 872059888EXAMGLOVF10W7

REF	Designation
655050	Gloves PE smooth transparent
655060	Gloves PE roughened
655111	Gloves latex medium white, powder free
655112	Gloves latex large white, powder free
655120	Gloves Synmax Vinyl, blue, Powder Free, Small
655121	Gloves Synmax Vinyl, blue, Powder Free, Medium
655122	Gloves Synmax Vinyl, blue, Powder Free, Large
655123	Gloves Synmax Vinyl, blue, Powder Free, XLarge
655130	Gloves Examination Nitrile, Blue, Powder free, size; XS
655131	Gloves Examination Nitrile, Blue, Powder free, size; S
655132	Gloves Examination Nitrile, Blue, Powder free, size; M
655133	Gloves Examination Nitrile, Blue, Powder free, size; L
655134	Gloves Examination Nitrile, Blue, Powder free, size; XL
655135	Gloves Examination Nitrile, Black, Powder free, size; XS
655136	Gloves Examination Nitrile, Black, Powder free, size; S
655137	Gloves Examination Nitrile, Black, Powder free, size; M
655138	Gloves Examination Nitrile, Black, Powder free, size; L
655139	Gloves Examination Nitrile, Black, Powder free, size; XL
655210	Gloves latex S per pair in white paper pouch powder free
655211	Gloves latex M per pair in white paper pouch powder free
655212	Gloves latex L per pair in white paper pouch powder free
655214	Gloves nitrile M per pair in paper pouch powder free blue
655215	Gloves nitrile L per pair in paper pouch powder free blue
655216	Gloves nitrile XL per pair in paper pouch powder free blue
655217	Gloves cotton M per pair
655218	Glove protection cotton L 240 mm white per pair
655219	Gloves cotton XL per pair
655220	Cotton gloves M per pair green
655221	Vinyl glove medium pair in wallet paper
655222	Vinyl glove large pair in wallet paper
655223	Cotton gloves S per pair green
655216	Gloves nitrile XL per pair in paper pouch powder free blue

To DoC number: DoC2156451TDC3

The medical devices which fall under the DoC are:

Product category: Personal protection equipment

Product family: Isolation gowns

Basic UDI-DI: 872059888ISOLGOWNF149K

REF	Designation
91003	Gown Isolation Polyethylene (CPE) blue, 98x125cm, elast.cuf
94000	Gown Isolation yellow, PP 25 g 115 x 136 cm, knitting cuff
94001	Gown Isolation yellow, PP 25 g 130 x 145 cm, knitting cuff
94002	Gown Isolation yellow, PP 25 g 140 x 155 cm, knitting cuff
94005W	Gown Isolation,white,PP+PE30gr,118x138cm knit cuff, coat
94101	Gown Isolation yellow,PP20g+PE15g hlf coat 115x136cm knt cuf
94102	Gown Isolation yellow,PP20g+PE15g hlf coat 130x145cm knt cuf
94103	Gown Isolation yellow,PP20g+PE15g hlf coat 140x155cm knt cuf
94200	Gown Isolation yellow, SMS 35 g 115 x 136 cm, knitting cuff
94201	Gown Isolation yellow, SMS 35 g 130 x 145 cm, knitting cuff
94202	Gown Isolation yellow, SMS 35 g 140 x 155 cm, knitting cuff
94300	Gown Isolation yellow,SMS35g 115x136cm, knt cuff us sleeves
94301	Gown Isolation yellow,SMS35g 130x145cm, knt cuff us sleeves
94302	Gown Isolation yellow,SMS35g 140x155cm, knt cuff us sleeves
94400	Gown Isolation yellow,SMS30g+PE15g,115x136cm,knt cuff us sl
94401	Gown Isolation yellow,SMS30g+PE15g,130x145cm,knt cuff us sl
94402	Gown Isolation yellow,SMS30g+PE15g,140x155cm,knt cuff us sl

Product category: Personal protection equipment

Product family: Mobcaps

Basic UDI-DI: 872059888MOBCAPSSF17Q6

REF	Designation
380	Bouffant muts blauw 56 cm, 14 g PP
382	Mobcap standard

Product category: Personal protection equipment

Product family: Shoe covers

Basic UDI-DI: 872059888SHOECOVF21YH

REF	Designation
235032	Cover shoe PE blue

To DoC number: DoC2156451TDC3

The medical devices which fall under the DoC are:

Product category: Personal protection equipment

Product family: Surgical gowns

Basic UDI-DI: 872059888SURGGOWNF24LC

REF	Designation
93554	Scrub suit SMS 35 gr/m2 Large blue
94993	Surgical gown SMS 45 g/m2, non-reinforced extra large length 146 cm
94997	Surgical gown SMS 45 g/m2, poly-reinforced extra large length 146 cm
95001	Surgical gown SMS 45 g/m2, non-reinforced medium length 131 cm
95002	Surgical gown SMS 45 g/m2, non-reinforced large length 142 cm
95003	Surgical gown SMS 45 g/m2, non-reinforced extra large length 152 cm
95004	Surgical gown SMS 45 g/m2, non-reinforced extra extra large length 160 cm
95011	Surgical gown SMS 35 g/m2, non-reinforced medium length 131 cm
95012	Surgical gown SMS 35 g/m2, non-reinforced large length 142 cm
95013	Surgical gown SMS 35 g/m2, non-reinforced extra large length 152 cm
95014	Surgical gown SMS 35 g/m2, non-reinforced extra extra large length 160 cm
95022	Surgical gown SMS 35 g/m2, poly-reinforced large length 142 cm
95023	Surgical gown SMS 35 g/m2, poly-reinforced extra large length 152 cm
95024	Surgical gown SMS 35 g/m2, poly-reinforced extra extra large length 160 cm
95032	Surgical gown SMS 45 g/m2, poly-reinforced large length 142 cm
95033	Surgical gown SMS 45 g/m2, poly-reinforced extra large length 152 cm
95034	Surgical gown SMS 45 g/m2, poly-reinforced extra extra large length 160 cm
95041	Surgical gown spunlaced 68 g/m2, non-reinforced medium length 131 cm
95042	Surgical gown spunlaced 68 g/m2, non-reinforced large length 142 cm
95043	Surgical gown spunlaced 68 g/m2, non-reinforced extra large length 152 cm
95050	Arm sleeve 2 ply 17 x 50,7 cm

Product category: Personal protection equipment

Product family: Face masks

Basic UDI-DI: 872059888FACEMASKF324Z

REF	Designation
10001	Mask paper 1 ply with elastic bands white
10005	Mask with earloops type II
10006	Mask with earloops type IIR

To DoC number: DoC2156451TDC3

The medical devices which fall under the DoC are:

Product category: Personal protection equipment

Product family: Hand towels

Basic UDI-DI: 872059888HANDTOWEF13PL

REF	Designation
71300	Towel tissue 2 ply 38 x 43 cm
71500	Towel tissue reinforced 37,5 x 51 cm
71800	Katoenen handdoek 43 x 68 cm

Signature:

Name:

Joana Pereira

Function:

Management representative

Place and Date:

Oss 20-11-2023