

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:

Examination gloves
Isolation gowns
Mobcaps
Shoe covers
Surgical gowns
Face masks
Hand towels

Intended purpose:

To use in the medical field to protect patient and user for cross-contamination

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 & 5

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: DoC2156451-2 The medical devices which fall under the DoC are:

Product category: **Examination gloves, Isolation gowns, Mobcaps, Shoe covers, Surgical gowns, Face masks, Hand towels**

REF	Designation	Basic UDI-DI	Trade name
380	Bouffant muts blauw 56 cm, 14 g PP	872059888MOBCAPSSF17Q6	medisp
382	Mobcap standard	872059888MOBCAPSSF17Q6	medisp
10001	Mask paper 1 ply with elastic bands white	872059888FACEMASKF324Z	medisp
93554	Scrub suit SMS 35 gr/m2 Large blue	872059888SURGGOWNF24LC	medisp
94000	Gown Isolation yellow, PP 25 g 115 x 136 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94001	Gown Isolation yellow, PP 25 g 130 x 145 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94002	Gown Isolation yellow, PP 25 g 140 x 155 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94101	Gown Isolation yellow,PP20g+PE15g hlf coat 115x136cm knt cuf	872059888ISOLGOWNF149K	medisp
94102	Gown Isolation yellow,PP20g+PE15g hlf coat 130x145cm knt cuf	872059888ISOLGOWNF149K	medisp
94103	Gown Isolation yellow,PP20g+PE15g hlf coat 140x155cm knt cuf	872059888ISOLGOWNF149K	medisp
94200	Gown Isolation yellow, SMS 35 g 115 x 136 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94201	Gown Isolation yellow, SMS 35 g 130 x 145 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94202	Gown Isolation yellow, SMS 35 g 140 x 155 cm, knitting cuff	872059888ISOLGOWNF149K	medisp
94300	Gown Isolation yellow,SMS35g 115x136cm, knt cuff us sleeves	872059888ISOLGOWNF149K	medisp
94301	Gown Isolation yellow,SMS35g 130x145cm, knt cuff us sleeves	872059888ISOLGOWNF149K	medisp
94302	Gown Isolation yellow,SMS35g 140x155cm, knt cuff us sleeves	872059888ISOLGOWNF149K	medisp
94400	Gown Isolation yellow,SMS30g+PE15g,115x136cm,knt cuff us sl	872059888ISOLGOWNF149K	medisp
94401	Gown Isolation yellow,SMS30g+PE15g,130x145cm,knt cuff us sl	872059888ISOLGOWNF149K	medisp
94402	Gown Isolation yellow,SMS30g+PE15g,140x155cm,knt cuff us sl	872059888ISOLGOWNF149K	medisp
94993	Surgical gown SMS 45 g/m2, non-reinforced extra large length 146 cm	872059888SURGGOWNF24LC	medisp
94997	Surgical gown SMS 45 g/m2, poly-reinforced extra large length 146 cm	872059888SURGGOWNF24LC	medisp
95001	Surgical gown SMS 45 g/m2, non-reinforced medium length 131 cm	872059888SURGGOWNF24LC	medisp
95002	Surgical gown SMS 45 g/m2, non-reinforced large length 142 cm	872059888SURGGOWNF24LC	medisp
95003	Surgical gown SMS 45 g/m2, non-reinforced extra large length 152 cm	872059888SURGGOWNF24LC	medisp
95004	Surgical gown SMS 45 g/m2, non-reinforced extra extra large length 160 cm	872059888SURGGOWNF24LC	medisp
95011	Surgical gown SMS 35 g/m2, non-reinforced medium length 131 cm	872059888SURGGOWNF24LC	medisp
95012	Surgical gown SMS 35 g/m2, non-reinforced large length 142 cm	872059888SURGGOWNF24LC	medisp
95013	Surgical gown SMS 35 g/m2, non-reinforced extra large length 152 cm	872059888SURGGOWNF24LC	medisp
95014	Surgical gown SMS 35 g/m2, non-reinforced extra extra large length 160 cm	872059888SURGGOWNF24LC	medisp
95022	Surgical gown SMS 35 g/m2, poly-reinforced large length 142 cm	872059888SURGGOWNF24LC	medisp
95023	Surgical gown SMS 35 g/m2, poly-reinforced extra large length 152 cm	872059888SURGGOWNF24LC	medisp
95024	Surgical gown SMS 35 g/m2, poly-reinforced extra extra large length 160 cm	872059888SURGGOWNF24LC	medisp
95032	Surgical gown SMS 45 g/m2, poly-reinforced large length 142 cm	872059888SURGGOWNF24LC	medisp
95033	Surgical gown SMS 45 g/m2, poly-reinforced extra large length 152 cm	872059888SURGGOWNF24LC	medisp
95034	Surgical gown SMS 45 g/m2, poly-reinforced extra extra large length 160 cm	872059888SURGGOWNF24LC	medisp
95041	Surgical gown spunlaced 68 g/m2, non-reinforced medium length 131 cm	872059888SURGGOWNF24LC	medisp
95042	Surgical gown spunlaced 68 g/m2, non-reinforced large length 142 cm	872059888SURGGOWNF24LC	medisp
95043	Surgical gown spunlaced 68 g/m2, non-reinforced extra large length 152 cm	872059888SURGGOWNF24LC	medisp
95050	Arm sleeve 2 ply 17 x 50,7 cm	872059888SURGGOWNF24LC	medisp
235032	Cover shoe PE blue	872059888SHOECOVEF21YH	medisp

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REF	Designation	Basic UDI-DI	Trade name
655050	Gloves PE smooth transparent	872059888EXAMGLOVF10W7	medisp
655060	Gloves PE roughened	872059888EXAMGLOVF10W7	medisp
655111	Gloves latex medium white, powder free	872059888EXAMGLOVF10W7	medisp
655112	Gloves latex large white, powder free	872059888EXAMGLOVF10W7	medisp
655120	Gloves Synmax Vinyl, blue, Powder Free, Small	872059888EXAMGLOVF10W7	medisp
655121	Gloves Synmax Vinyl, blue, Powder Free, Medium	872059888EXAMGLOVF10W7	medisp
655122	Gloves Synmax Vinyl, blue, Powder Free, Large	872059888EXAMGLOVF10W7	medisp
655123	Gloves Synmax Vinyl, blue, Powder Free, XLarge	872059888EXAMGLOVF10W7	medisp
655130	Gloves Examination Nitrile, Blue, Powder free, size; XS	872059888EXAMGLOVF10W7	medisp
655131	Gloves Examination Nitrile, Blue, Powder free, size; S	872059888EXAMGLOVF10W7	medisp
655132	Gloves Examination Nitrile, Blue, Powder free, size; M	872059888EXAMGLOVF10W7	medisp
655133	Gloves Examination Nitrile, Blue, Powder free, size; L	872059888EXAMGLOVF10W7	medisp
655134	Gloves Examination Nitrile, Blue, Powder free, size; XL	872059888EXAMGLOVF10W7	medisp
655210	Gloves latex S per pair in white paper pouch powder free	872059888EXAMGLOVF10W7	medisp
655211	Gloves latex M per pair in white paper pouch powder free	872059888EXAMGLOVF10W7	medisp
655212	Gloves latex L per pair in white paper pouch powder free	872059888EXAMGLOVF10W7	medisp
655214	Gloves nitrile M per pair in paper pouch powder free blue	872059888EXAMGLOVF10W7	medisp
655215	Gloves nitrile L per pair in paper pouch powder free blue	872059888EXAMGLOVF10W7	medisp
655216	Gloves nitrile XL per pair in paper pouch powder free blue	872059888EXAMGLOVF10W7	medisp
655217	Gloves cotton M per pair	872059888EXAMGLOVF10W7	medisp
655218	Glove protection cotton L 240 mm white per pair	872059888EXAMGLOVF10W7	medisp
655219	Gloves cotton XL per pair	872059888EXAMGLOVF10W7	medisp
655220	Cotton gloves M per pair green	872059888EXAMGLOVF10W7	medisp
655221	Vinyl glove medium pair in wallet paper	872059888EXAMGLOVF10W7	medisp
655222	Vinyl glove large pair in wallet paper	872059888EXAMGLOVF10W7	medisp
655223	Cotton gloves S per pair green	872059888EXAMGLOVF10W7	medisp
71300	Towel tissue 2 ply 38 x 43 cm	872059888HANDTOWEF13PL	medisp
71500	Towel tissue reinforced 37,5 x 51 cm	872059888HANDTOWEF13PL	medisp
71800	Katoenen handdoek 43 x 68 cm	872059888HANDTOWEF13PL	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date:

PART OF STI GROUP

