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| <b>Manufacturer:</b>  | Sterisets International B.V.<br>Menhirweg 16   5342 LS Oss<br>The Netherlands<br>P +31 (0)412 667 755<br>E info@sterisets.com<br>www.sterisets.com |
| <b>SRN:</b>   | NL-MF-000030883  |
| <b>Product category:</b>  | Personal protection equipment  |
| <b>Product families:</b>  |  |
| <u>Designation:</u><br>Examination gloves<br>Isolation gowns<br>Mobcaps<br>Shoe covers<br>Surgical gowns<br>Face masks<br>Hand towels | <u>Intended purpose:</u><br>To use in the medical field to protect patient and user for cross-contamination  |
| <b>Risk classification:</b>   | Class I  |
| <b>Rule:</b>  | 1 & 5  |
| <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 03-04-2025

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               |

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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 03-04-2025