

|                                     |  |
|-------------------------------------|--|
| <b>Manufacturer:</b>                | Sterisets International B.V.<br>Ketelmeer 3 – 5347 JX Oss, The Netherlands<br>Tel: +31 412 667 755 Email info@sterisets.com<br>www.sterisets.com |
| <b>Medical devices:</b>             |  |
| <b>Designation:</b>                 | <b>Intended purpose:</b>   |
| Plastic instruments                 | To hold and compress medical devices during manipulation   |
| <b>Risk Class:</b>                  | According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.<br>Class I |
| <b>Rule:</b>                        | 1  |
| <b>Conformity assessment route:</b> | Annex IX   |
| <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:** Jos van der Kwartel

**Function:** Management representative

**Place and Date:**

To DoC number: DoC2156451-3 The medical devices which fall under the DoC are:

Product category: **Plastic instruments**

| REF   | Designation                                  | Basic UDI-DI           | Trade name |
|-------|--|------------------------|------------|
| 5801  | Forceps sponge nylon 20 cm blue              | 872059888FORCLSCIF11TV | medisp     |
| 5802  | Forceps sponge nylon 24 cm blue              | 872059888FORCLSCIF11TV | medisp     |
| 5803  | Forceps Pean plastic 12 cm blue              | 872059888FORCLSCIF11TV | medisp     |
| 5804  | Forceps sponge nylon 24 cm blue extra strong | 872059888FORCLSCIF11TV | medisp     |
| 5805  | Klem kunststof 10 cm groen                   | 872059888FORCLSCIF11TV | medisp     |
| 5806  | Forceps Kiel clamp plastic green 13 cm       | 872059888FORCLSCIF11TV | medisp     |
| 5810  | Pincet fogless 13 cm groen                   | 872059888FORCLSCIF11TV | medisp     |
| 5812  | Forceps Pean clamp plastic green 12,5 cm     | 872059888FORCLSCIF11TV | medisp     |
| 5813  | Forceps Pean clamp nylon 13,5 cm blue        | 872059888FORCLSCIF11TV | medisp     |
| 5817  | Forceps Kiel clamp plastic red 13 cm         | 872059888FORCLSCIF11TV | medisp     |
| 5829  | Forceps Medisp plastic green 14 cm           | 872059888FORCLSCIF11TV | medisp     |
| 5830  | Forceps 13,8 cm white                        | 872059888FORCLSCIF11TV | medisp     |
| 5831  | Forceps 13,8 cm blue                         | 872059888FORCLSCIF11TV | medisp     |
| 5840  | Forceps Burger plastic green 12,5 cm         | 872059888FORCLSCIF11TV | medisp     |
| 5842  | Forceps 12,5 cm burger white                 | 872059888FORCLSCIF11TV | medisp     |
| 5844  | Forceps 12,5 cm burger blue                  | 872059888FORCLSCIF11TV | medisp     |
| 5846  | Forceps 12,5 cm burger red                   | 872059888FORCLSCIF11TV | medisp     |
| 5895  | Clamp towel plastic white 6,5 cm             | 872059888FORCLSCIF11TV | medisp     |
| 5999  | Clamp catheter plastic white                 | 872059888FORCLSCIF11TV | medisp     |
| 5803K | Pean kunststof 12 cm blauw                   | 872059888FORCLSCIF11TV | medisp     |
| 5830M | Forceps white 13,8 cm                        | 872059888FORCLSCIF11TV | medisp     |
| 5840M | Forceps burger green 12,5 cm                 | 872059888FORCLSCIF11TV | medisp     |
| 5905T | Clamp catheter plastic                       | 872059888FORCLSCIF11TV | medisp     |
| 5906T | Screw clamp grey                             | 872059888FORCLSCIF11TV | medisp     |

**Signature:**

**Name:** Jos van der Kwartel

**Function:** Management representative

**Place and Date:**