

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:

Spatulas
Washing gloves
Tourniquets
Cleaning foam stick

Intended purpose:

To facilitate examination of surrounding organs and tissues

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: DoC2156451-10 The medical devices which fall under the DoC are:

Product category: **Spatulas, Washing gloves, Tourniquets, Cleaning foam stick**

| REF | Designation | Basic UDI-DI | Trade name |
|---------|--|------------------------|------------|
| 5874 | Foam (white) stick (green),15 cm, ultra-sonic sealed,bulk NS | 872059888CLEANFOAF5GT | medisp |
| 5875 | Lollyprep with handle | 872059888CLEANFOAF5GT | medisp |
| 5876 | Foam stick dental green 15 cm bulk | 872059888CLEANFOAF5GT | medisp |
| 5880 | Lollyprep with handle 16 cm | 872059888CLEANFOAF5GT | medisp |
| 58755 | Desinfectiedepper foam | 872059888CLEANFOAF5GT | medisp |
| 71000 | Washing glove 16 x 23 cm | 872059888WASHGLOVF295H | medisp |
| 215014 | Tongue depressor woden 140 x 14 x 1,6 mm | 872059888SPATULASF22AX | medisp |
| 215058 | Tourniquet 49 x 3,0 cm folded including silicone band | 872059888TOURNIQUF35RG | medisp |
| 215059 | Tourniquet 49 x 2,5 cm folded including silicone band | 872059888TOURNIQUF35RG | medisp |
| 4389T | Foam sponge white | 872059888CLEANFOAF5GT | medisp |
| 5875SM | Lollyprep with handle | 872059888CLEANFOAF5GT | medisp |
| 5876NS5 | Foam sticks dental green 15 cm per 5 | 872059888CLEANFOAF5GT | medisp |

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: