

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:

Suture bags
Waste bags

Intended purpose:

To contain used medical devices after treatment

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

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: DoC2156451-11 The medical devices which fall under the DoC are:

Product category: **Suture bags, Waste bags**

REF	Designation	Basic UDI-DI	Trade name
95838	Bag suture paper white 16x30,5cm 1 strip dble adh tape	872059888SURGGOWNF24LC	medisp
95839	Bag suture with adhesive sterisets logo	872059888SURGGOWNF24LC	medisp
215100	Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive ETO/ RAD	872059888WASTEBAGF30WU	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: