

## **EU Declaration** of Conformity

**Manufacturer:** Sterisets International B.V.

Menhirweg 16 I 5342 LS Oss

The Netherlands P +31 (0)412 667 755 E info@sterisets.com www.sterisets.com

**SRN:** NL-MF-000030883

**Product category:** Waste bags

**Product families:** 

<u>Designation:</u> <u>Intended purpose:</u>

Suture bags To contain used medical devices after treatment

Waste bags

**Risk classification:** Class I

Rule: 1

Conformity assessment route: Annex II and III
Common specifications: Not applicable

**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.

1/2

Signature:

Name: Joana Pereira

**Function:** Management representative

Place and Date: Oss 03-04-2025

Sterisets International

PART OF STI GROUP





To DoC number: DoC2156451TDC11

The medical devices which fall under the DoC are:

**Product category:** Waste bags <u>Product family:</u> Suture bags

Basic UDI-DI: 872059888SUTURBAGF25MM

| REF   | Designation  |
|-------|--|
| 95838 | Bag suture paper white 16x30,5cm 1 strip dble adh tape |
| 95839 | Bag suture with adhesive sterisets logo                |

**Product category:** Waste bags <u>Product family:</u> Waste bags

Basic UDI-DI: 872059888WASTEBAGF30WU

| REF    | Designation   |
|--------|---|
| 215100 | Bag HDPE 0.025 x 30 x 42.5 cm Yellow w/ adhesive ETO/ RAD |

Signature:

Name: Joana Pereira

**Function:** Management representative

Place and Date: Oss 03-04-2025



2/2