

DoC2025/40PG1B00

Issued: 14-08-2026

Manufacturer:

Sterisets International B.V.
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Model Template:

Annex VIII, Regulation (EU) 2025/40 on packaging and packaging waste (Article 39).

1. Packaging Identification

Refer to Annex 1.

2. Object of declaration:

The present declaration of conformity is issued under the sole responsibility of the manufacturer.
This declaration applies to a family of packaging units sharing identical material, design and manufacturing process, varying only in size to accommodate different quantities of units.

We hereby declare that the packaging covered by this declaration is in conformity with the relevant Union harmonisation legislation and standards:

Regulation (EU) 2025/40 on packaging and packaging waste
Regulation (EC) No 1907/2006 - REACH

This declaration is based on the technical information available as of the date of its issuance and may be revised in the event of changes to applicable legislation, the raw materials used, or the information provided by suppliers.

This declaration and the technical documentation will be retained for 5 years.

3. Requirements of Regulation (EU) 2025/40

Article	Requirement	Compliant
5.	Requirements for substances in packaging	Yes
6.	Recyclable packaging	N/A ³
7.	Minimum recycled content in plastic packaging	N/A ³
8.	Biobased feedstock in plastic packaging	N/A
9	Compostable packaging	N/A
10	Packaging minimization	In progress ¹
11	Reusable packaging	N/A
12	Labelling of packaging	In progress ²

¹ Transitional period;

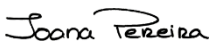
² Pending implementing act;

³ Contact- sensitive packaging of medical devices covered by regulation EU 2017/745 shall not apply article 6 and 7 of PPWR regulation.

Annex 1

The packaging units that fall under this DoC are:

Packaging Identification	Pouch composed of a paper layer on one side and PET/PP laminated film on the other, in direct contact with the product and forming the sales unit.
Packaging Type	Sales packaging Single-use
Products with this packaging include:	Sterile catheterization accessory sets, sterile single use forceps, clamps and scissors, sterile and non sterile dressing sets, sterile dialysis sets, sterile delivery sets, sterile surgical sets, sterile washing sets, sterile suture accessory sets. Sterile instruments and sterile trays and bowls.

Signature: 
Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel, 14-08-2026