SPS MEDICAL
A MEMBER OF THE STERIMED GROUP

DECLARATION OF CONFORMITY

We, SPS Medical SAS, 5 rue de Montigny, zone industrielle, 77120 COULOMMIERS, FRANCE.

Considered as a Medical Device Manufacturer, registered under reference number FR-MF-000012699 in EUDAMED database

Hereby certify, under our sole responsibility, that the following products:

SEALABLE POUCHES AND REELS FOR STERILIZATION

- Are a Class I non-invasive medical device, according to definitions and rule 1 of classification on the Annex VIII of 2017/745 EU MDR.
- Are intended to be used as preformed sterile barrier system according to ISO 11607-1 v2019 standard, delivered non-sterile and used for sterilization packaging of medical devices in hospitals and healthcare facilities
- GMDN code 13735 (Sterilization packaging, single use)

The range of products is listed below:

Range	Item code (*)	Property	Basic UDI-DI N°
Flat Pouches BOP TI	S2T	Triple Indicators	3662102JA01SB
Flat Reels BOP TI	G2T	Triple Indicators	3662102JB01SG
Gusseted Pouches BOP TI	S2F	Triple Indicators	3662102JC01SM
Gusseted Reels BOP TI	G2F	Triple Indicators	3662102JD01SS
Self seal Pouches BOP DI	S2A	Double Indicator Auto- Adhesive	3662102JE01SX

(*) Product codes (Full product code is based on the ten (10) digits, the last 5 or 4 additional digits indicating the size of the pouch/reel).

- Comply with the general safety and performance requirements of the European Medical device Regulation 2017/745 (MDR) as demonstrated in technical file: TF-08 Revision 01.

The conformity assessment procedure was established according to:

- Article 52. §7 after drawing up the technical documentation set out in Annexes II and III of the MDR 2017/745.

Expiration Date of this declaration: 2028-02-09,

This declaration of conformity is valid in relation to the batch release document corresponding of manufactured products.

SPS Medical – Thursday, 09 February 2023

N.Marchand / Regulatory Affairs

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