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	BUDI N°
ULTRA pouches	98ULT / SUL / SUS	Single indicator	3662102IA01S4
ULTRA reels	99ULT / GUL	Single indicator	3662102IA02S6

(*) 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-01 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: 2027-03-21,

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

SPS Medical - Thursday, 21 March 2022

Marchand Nathalie / Regulatory Affairs

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A MEMBER OF THE STERIMED GROUP
5 rue de Montigny
Zone Industrielle - 77120 COULOMMIERS
Tél. 01 64 75 60 00 - Fax 01 64 75 60 07
Siret 321 716 847 00025