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

SPS MEDICAL
A MEMBER OF THE STERIMED GROUP

SPS Medical
5, rue de Montigny Z.I. – 77120 Coulommiers France
Tél. : +33 (0)1 64 75 60 00 – Fax : +33 (0)1 64 75 60 07
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

Customer: DUTSHER

STATEMENT

We, SPS Medical SAS, 5 rue de Montigny, zone industrielle, 77120 COULOMMIERS, FRANCE.
Declares for the following products:

BOP TI range products referenced:

Gamme	Code Produit (*)	Propriété
Gusseted Reels BOP TI	G2Fxxxxxxx	Triple Indicators

Cytotoxicity :

The medical paper and the film used in the composition of these products meets the requirements of USP Chapter <87> for non-toxicity when tested according to the ISO 10993-5 method for MEM elution cytotoxicity.

California Proposition 65 :

That none of the chemicals listed in the California "Safe drinking water and toxic enforcement act of 1986", from January 03, 2020 are used or not intentionally used as raw material in the manufacturing of the product, however substances under form of traces can not be excluded as the following :

SUBSTANCES	CAS
Chromium/ Lead/ Cadmium / Mercury	/
Arsenic	7440-38-2
Toluene	108-88-3
Menthanol	67-56-1
Formaldehyde	50-00-0
Epîchlorhydrin	106-89-8
3-chloropropane-1.2-diol	96-24-2
Dichloro-2-propanol-1.3	96-23-1
Acetaldehyde	75-07-0
Phenol	108-95-2
Diethalonamine	111-42-2
Propylene oxide	75-56-9
1.4-dioxane	123-91-1
PCB'S Inadvertently generated impurities	1336-36-3
Cobalt	7440-48-4
Furan	110-00-9

Moreover, m-tolylidene diisocyanate CAS26471-62-5 is known as substance used in the adhesive part for film lamination.
According to the analysis, the presence of this substance is less than 0.1% (0.000001836% /m²) of the plastic film part of the final product referenced earlier in this document.

TSE/ BSE – Animal origin material :

PP film: The tallow derived from the raw material used in PP (Polypropylene), complies with the requirements of explanatory note EMEA/410/01 Rev 3 part 6.4 (tallow derivatives).

Paper : is formulated without the addition of direct material of animal origin. However, according to our supplier, certain raw materials used include materials of animal origin processed according to strict standards and processes as defined in Annex VI, Chapter III of Regulation 1774/2002. As such, these raw materials are unlikely to present any TSE risk.

Not contain intentionally :

- **Latex** /Natural Rubber
- **Phtalates**
- **Nitrosamines**
- **Allergens** according to directive EU No.1169/2011 of 25 Oct 2011
- **Bisphenols**
- **Formaldehyde**
- **Human blood Derivatives**
- **Medicinal or drugs substances**
- **Nanomaterials**
- **PFAS**

- **Endocrine Disruptors** : our supplier inform that traces of DBP (Dibutylphthalate) may be present as catalyst modifier residues which would not exceed 1ppm.

- **CMR substances** : CMR 1 A, CMR1B and CMR2 - CMR 1 A, CMR1B and CMR2 -Does not contain substances classified as carcinogenic, mutagenic or toxic for reproduction of category 1A and 1B according to table 3.1 of appendix VI of European regulation N° 1272/2008, above the threshold of 0.1%. Given the composition and manufacturing process of the film, the residual presence of such components in this material cannot be excluded.

All of these data are based on those received from our Suppliers, no routine analysis is carried out by SPS Medical.

Coulommiers, 29/01/2025

DONGMO METENOU Danick/Quality

Signature :

SPS MEDICAL
5 rue de Montigny
Zone Industrielle - 77120 COULOMMIERS
Tél. 01 64 75 60 00 - Fax 01 64 75 60 07

Customer : DUTSHER

STATEMENT

We, SPS MEDICAL, 5 rue de Montigny, ZI, Coulommiers 77120, ensures for the following articles:

Gamme	*Code Produit (*)*	*Propriété*
Gusseted Reels BOP TI	*G2Fxxxxxxx*	*Triple Indicators*

These products are not in the scope of the European Directive on the restriction on the use of certain hazardous substances in electrical and electronic equipement (2011/65/EC – RoHS2, amended by EU 2015/863 - RoHS3 and EU 2017/2102).

However, the product complies with the requirements regarding to maximum concentration of the following 6 substances (1000 ppm by weight of homogeneous material (except for cadnium, which is limited to 100 ppm).

- Lead,
- Cadmium,
- Mercury,
- Hexavalent Chromium,
- Polybrominated Biphenyls (PBBs),
- Polybrominated Diphenylethers (PBDEs)

Moreover, to the best of our knowledge, no kind of phthalates plasticizers are intentionnaly used in the formulations of raw material, however, we can not exclude trace of Butyl Benzyl phthalate (BBP) as catalyst of modifier residues (would not exceed 1 ppm)

HEAVY METALS :

According to our manufacturer, materials used are manufactured in compliance with Directive 94/62/EC on Packaging and Packaging Waste, as amended.

More specifically, the combined total amount of Lead, Cadmium, Mercury and hexavalent Chromium in abovementioned material does not exceed 100 ppm and no substances dangerous to the environment are purposely used in manufacturing our product.

All of this data are based on those transmitted by our suppliers, no routine analysis is carried out by SPS Médical.

Coulommiers, 29/01/2025

DONGMO METENOU Danick/Quality

SPS MEDICAL Coulommiers
5, rue de Montigny - Zone Industrielle - 77120 Coulommiers France
Tél. : +33 (0)1 64 75 60 00 – Fax : +33 (0)1 64 75 60 07