Plastod S.p.A.

Via Walter Masetti, 7
40012 - Lippo di Calderara di Reno
Bologna - ITALY

Capitale Sociale € 3.857.144,00 I.V.

PLASTOD
Advanced Wound Care

P.IVA - VAT IT00497271205
C.F. 00283420370

SDI: 7HE8RN5
R.E.A. Bologna 92164

N. Mecc. BO017328
Aut. Ministeriale 3554/P

DECLARATION OF CONFORMITY FOR THE FAMILY OF MEDICAL DEVICES "MECHANICAL BARRIER WOUND DRESSINGS FOR EXUDATES ABSORPTION"

whose trade names are specified in the annex, to the General Safety and Performance Requirements referred to in Annex I of Regulation (EU) 2017/745 on medical devices and subsequent amendments and corrections.

The undersigned PLASTOD S.p.A., with registered office in Via Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) - Italy, Single registration number (SRN) of the manufacturer: 8015143, manufacturer of the devices called "MECHANICAL BARRIER WOUND DRESSINGS FOR EXUDATES ABSORPTION" whose trade names are shown in the annex,

declares under its own responsibility that the devices referred to in the object meet all the General Safety and Performance Requirements required by Annex I of Regulation (EU) 2017/745 and subsequent amendments and corrections.

For this purpose, it guarantees and declares under its own responsibility the following:

1. That the devices in question meet the applicable provisions of Regulation (EU) 2017/745 and subsequent amendments and corrections, as required by the procedure of Article 52 "Conformity assessment procedures", point 7 of the aforementioned Regulation.
2. That the devices in question are to be considered as belonging to Class I according to Rule 4, first indent of Annex VIII of Regulation (EU) 2017/745.
3. That the devices in question are put on the market in NON-STERILE packaging.
4. That the devices are produced in various versions and the list of corresponding commercial names is attached.
5. That the design and manufacturing process is conducted in compliance with the requirements of the company's Quality Management System, in accordance with the requirements of Annex IX of Regulation (EU) 2017/745.
6. That PLASTOD S.p.A. undertakes to preserve and keep available to the Competent Authority the product Technical Documentation, specified in Annexes II and III of Regulation (EU) 2017/745, for a period of at least eight years from the last date of placing on the market of the last batch of the product.
7. That the devices comply with the state of the art requirements referred to in the standards mentioned in the current edition of the Technical Documentation.
8. That the company's Quality Management System complies with the UNI EN ISO 9001: 2015 standards (ref. Certificate n. 2100, current issue of 08/01/2020) and UNI EN ISO 13485: 2016 (ref. Certificate n. 9605, current issue of 08/01/2020).
9. That PLASTOD S.p.A. has already notified the Italian Competent Authority of the placing on the market of the aforementioned devices. It also declares to have established and to maintain an appropriate procedure to ensure the post-marketing surveillance required by Regulation (EU) 2017/745 on medical devices.

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The content of this declaration of conformity, issued under the sole responsibility of the manufacturer PLASTOD S.p.A., is confirmed at each code release and at each batch release of the indicated devices, produced starting from 03/05/2021.

This declaration is valid for a maximum of five years from the date of issue.

Attachments:

– List of trade names referred to in this Declaration.

In witness whereof

PLASTOD S.p.A.

On behalf of the Legal Representative

Umberto Dotta (BoD Vice-President)

Place, date of issue and Ed / Rev. of the declaration:

Lippo di Calderara di Reno, 03/05/2021 - Ed./Rev. 01/0