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, 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 10 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. 19344-A, current issue of 30/07/2021) and UNI CEI EN ISO 13485: 2016 (ref. Certificate n. 19344-M, current issue of 30/07/2021).
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 30/07/2021.

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, 30/07/2021 - Ed./Rev. 01/1

PLASTOD Advanced Wound Care	Tipo di documento: LISTA PRODOTTI/ PRODUCTS LIST	Data prima edizione: 03/05/21
		Numero: Annex I TD 01-1
		Ed / Rev: 01/1 del 30/07/21
Prodotto: Medicazioni di barriera meccanica per assorbimento di essudati (TD 01-1) – Mechanical barrier wound dressings for exudates absorption		
Famiglia prodotti: Dispositivi medici - medicazioni		

Fabbricante: Manufacturer PLASTOD S.p.A., Via W. Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) – Italia

Distributore: Distributor PLASTOD S.p.A., Via W. Masetti, 7 - 40012 Lippo di Calderara di Reno (BO) – Italia

Codice Plastod Plastod code	REF	Marchio Brand	Descrizione Description	Dimensione Size	Scheda tecnica TDS	Confezione (pz/astuccio) Box (pcs/box)	BASIC UDI-DI
CT0120ZP	03030	Zip Strip	Strip in PE trasparente	19x72 mm	66-721	20	8015143M04010102GZ
CR0120FA-3	00212	Farmaplasto	Strip in PE rosa	19x72 mm	66-622	20	8015143M04010102GZ
CR0212FA-3	00214	Farmaplasto	Strip in PE rosa	25x72 mm	66-622	12	8015143M04010102GZ
CR40ASFA-3	00216	Farmaplasto	Strip in PE rosa	19x72, 25x72, diam.22, 9x38, 38x38 mm	66-622	40	8015143M04010102GZ
CR20ASFA-3	00218	Farmaplasto	Strip in PE rosa	19x72, 25x72, diam.22, 9x38 mm	66-622	20	8015143M04010102GZ
CR010CFA-3	00220	Farmaplasto	Strip in PE rosa	19x72 mm	66-622	100	8015143M04010102GZ
CA17150FA-3	00221	Farmaplasto	Strip in PE blu	25x72 mm	66-833	150	8015143M04010102GZ
CB200MFA-3	00225	Farmaplasto	Strip in TNT estensibile rosa	19x72 mm	67-422	1000	8015143M04010101GX
CR4250FA-3	00226	Farmaplasto	Strip in PE rosa	diam 22 mm	66-112	250	8015143M04010102GZ
CA201MFA-3	00227	Farmaplasto	Strip in PE blu	19x72 mm	66-833	1000	8015143M04010102GZ
CS0120FA-3	00232	Farmaplasto	Strip TNT estensibile bianco	19x72 mm	67-222	20	8015143M04010101GX
CS40ASFA-3	00234	Farmaplasto	Strip TNT estensibile bianco	19x72, 25x72, diam.22, 9x38, 38x38 mm	67-222	40	8015143M04010101GX
US6100FA-3	00247	Farmaplasto	Benda adesiva in TNT estensibile bianco	mt 1x6 cm	61-222-7	1	8015143M04010101GX
UO6100NFA-3	00249	Farmaplasto	Benda adesiva in elastico	mt 1x6 cm	61-822-7	1	8015143M04010199JA
CTI15ASFA-3	00281	Farmaplasto BWT	Strip in film trasparente in PU	19x72, 25x72, diam.22,38x38 mm	69-012	15 assortito	8015143M04010102GZ
CTI0112FA-3	00283	Farmaplasto BWT	Strip in film trasparente in PU	19x72 mm	69-012	12	8015143M04010102GZ
US4500FA-3	00360	Farmaplasto	Benda adesiva in TNT estensibile bianco	mt 5x4 cm	61-222-7	1	8015143M04010101GX
US6500FA-3	00362	Farmaplasto	Benda adesiva in TNT estensibile bianco	mt 5x6 cm	61-222-7	1	8015143M04010101GX
US8500FA-3	00364	Farmaplasto	Benda adesiva in TNT estensibile bianco	mt 5x8 cm	61-222-7	1	8015143M04010101GX

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CC24ASAI-3	03000	Adhesan Strong Protection	Strip in PE foam rosa	19x72, 25x72 mm	68-522	24	8015143M04010102GZ
CR30ASAI-3	03002	Adhesan waterproof mix	Strip in PE rosa	19x72, 25x72, 57x16, diam22 mm	66-622	30	8015143M04010102GZ
CB16ASAI-3	03006	Adhesan Special Shapes	Strip in TNT estensibile rosa	articolazione	67-422	16	8015143M04010101GX
CFG5012AI-3	03008	Adhesan Kids Tattoo	Strip in film trasparente in PU stampato tattoo	25x57 mm	69-212	12	8015143M04010102GZ
CF20ASAI-3	03010	Adhesan children	Strip in PE stampato clown - bears	19x72 mm	66-922	20	8015143M04010102GZ
CO20ASAI-3	03014	Adhesan High Confort	Strip in elastico rosa	19x72, 25x72 mm	67-122	20	8015143M04010199JA