PLASTOD
Advanced Wound Care

PLASTOD S.p.A.
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DECLARATION OF CONFORMITY FOR THE RANGE OF MEDICAL DEVICES "BIATAIN CONTACT ADVANCED WOUND CONTACT LAYER DRESSINGS"

to the essential requirements defined in Annex I of Directive 93/42/EEC and further integrations as per Directive 2007/47/EC. The relative business names are specified in the attached file.

Plastod S.p.A., located in Via Masetti, 7 – 40012 Lippo di Calderara di Reno (BO) - Italy, manufacturer of the medical devices named "BIATAIN CONTACT ADVANCED WOUND CONTACT LAYER DRESSINGS" of which business names are reported in the attachment,

hereby declares under its own responsibility that these devices satisfy all the essential requirements set forth in Annex I, Directive 93/42/EEC and following integrations as per Directive 2007/47/EC.

To this purpose it guarantees and declares under its own responsibility that:

1. The devices satisfy the Directive 93/42/EEC applicable previsions and Directive 2007/47/EC (and their Italian implementation) in compliance with Annex II procedures.
2. The devices have to be considered as Class II B according to rule 4, Annex IX of the mentioned Directives.
3. The devices are marketed in STERILE and NON STERILE packaging.
4. The devices are produced in various versions and the corresponding list of business names is reported in the attachment.
5. The planning and manufacturing procedure is managed in accordance with the Company Quality System, in compliance with the prevision of Annex II of the mentioned Directives.
6. Plastod S.p.A. undertakes to keep the product Technical File, specified in Annex II of the mentioned Directives, at the Competent Authority's disposal for a period of 10 years starting from the market release date of the final product batch.
7. The devices respect the standard requirements mentioned in the current edition of the Technical file.
8. The devices are manufactured and marketed as indicated in the product technical file within the context of the application of a Company Quality System declared as compliant by company CERTIQUALITY, a Notified Body pursuant to Directive 93/42/EEC and Directive 2007/47/EC with the number 0546 in accordance with Annex II of the mentioned Directives (ref. Certificate n° 27516, first issue 23/02/2005, current issue dated 08/01/2020 valid until 26/05/2024). It is also declared that the quality system adopted for the planning and the manufacturing of all devices is in compliance with UNI EN ISO 9001:2015 (ref. Certificate n° 19344-A, current issue 30/07/2021) and UNI CEI EN ISO 13485:2016 (ref. Certificate n° 19344-M, current issue 30/07/2021).
9. Plastod S.p.A. has already notified the Italian Competent Authority about the market release of said devices. It also declares the it has set up and maintains a suitable procedure to guarantee post – sale survey as requested by Directive 93/42/EEC and Directive 2007/47/EC and their Italian implementation.

The contents of this declaration of conformity are confirmed at every code issue and every batch release of the indicated devices manufactured from 30/07/2021. This declaration is issued alongside the Notified Body's certificate renewal and it is valid for up to five years from its issuing date.

Attachments:

- Copy of CE mark certificate;
- List of business names to which this Declaration refers.

In witness whereof

Umberto Dotta
The Legal Representative

Declaration issue date: 30/07/2021 Ed./Rev. 01/1

PLASTOD S.p.A. 30/07/2021

MEDICAZIONI AVANZATE IN RETINA ANTIADERENTE
ADVANCED WOUND DRESSINGS AS ANTIADHERING NET (WOUND CONTACT LAYER)

Codifica di commercializzazione
Commercial codes

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DISTRIBUTORS INDEX

PLASTOD S.p.A. 30/07/2021

MEDICAZIONI AVANZATE IN RETINA ANTIADERENTE

ADVANCED WOUND DRESSINGS AS ANTIADHERING NET (WOUND CONTACT LAYER)

Codifica di commercializzazione

Commercial codes

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

Distributore: *Distributor* COLOPLAST A/S, Holtedam 1 - 3050 Humlebaek -Denmark

Codice Plastod *Plastod code*	**Codice comm.** *REF code*	**Marchio** *Brand*	**Descrizione** *Description*	**Dimensione** *Size*	**Scheda tecnica** *TDS*	**Confezione (pezzi/astuccio)** *Box (pcs/box)*
GCT00603BC	33565-0	BIATAIN Contact	Medicazione in rete antiaderente in silicone trasparente, sterile EO *Wound contact layer dressing in silicone, EO sterile*	10x20 cm	94-500-3 94-000	3
GCT01303BC	33566-0	BIATAIN Contact		15x15 cm		3
GCT01310BC	33566-1	BIATAIN Contact		15x15 cm		10
GCT01705BC	33563-0	BIATAIN Contact		15x25 cm		5
GCT03105BC	33561-1	BIATAIN Contact		7.5x10 cm		5
GCT03110BC	33561-0	BIATAIN Contact		7.5x10 cm		10
GCT03160BC	33561-2	BIATAIN Contact		7.5x10 cm		60
GCT03205BC	33562-1	BIATAIN Contact		10x18 cm		5
GCT03210BC	33562-0	BIATAIN Contact		10x18 cm		10
GCT03305BC	33564-0	BIATAIN Contact		18x30 cm		5
GCT03405BC	33560-1	BIATAIN Contact		5x7.5 cm		5
GCT03410BC	33560-0	BIATAIN Contact		5x7.5 cm		10
GCT03460BC	33560-2	BIATAIN Contact		5x7.5 cm		60