PLASTOD S.p.A.
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DECLARATION OF CONFORMITY FOR MEDICAL DEVICE RANGE
"STERILE PLASTERS AND WOUND DRESSINGS"

to the essential requirements defined in Annex I of Directive 93/42/CEE and further integrations as per Directive 2007/47/CE. 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 "STERILE PLASTERS AND WOUND 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/CEE and following integrations as per Directive 2007/47/CE.

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

1. The devices satisfy the Directive 93/42/CEE applicable previsions and Directive 2007/47/CE (and their Italian implementation) in compliance with Annex VII and Annex V procedures.
2. The devices have to be considered as Class I according to rules 1 and 4, Annex IX of the mentioned Directives.
3. The devices are marketed in 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 VII and Annex V of the mentioned Directives.
6. Plastod S.p.A. undertakes to keep the product Technical File, specified in Annex VII of the mentioned Directives, at the Competent Authority's disposal for a period of at least eight 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/ECC and Directive 2007/47/CE with the number 0546 in accordance with Annex V of the mentioned Directives (ref. Certificate n° 25043, first issue 23/02/1998, current issue dated 10/01/2018 valid until 09/01/2023). 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 9001:2008 (ref. Certificate n° 2100, current issue 07/01/2016) and UNI EN ISO 13485:2012 (ref. Certificate n° 9605, current issue 04/01/2017).
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/CEE and Directive 2007/47/CE 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 08/03/2018. 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
PLASTOD S.p.A.

Giorgio Dotta
The Legal Representative

Declaration issue date: 08/03/2018 Ed./Rev. 05/1