



DECLARATION OF CONFORMITY OF MEDICAL DEVICES NAMED:

REF: 2XXXX, 2XXXXX, 2XXXXXX, 4XXXX, 4XXXXX, 5XXXX, 5XXXXX, 6XXXX, 8XXXX, 8XXXXX

Description Compresse piegate in Garza o TNT, sterili e non sterili (Famiglia F041, F042, F043, F044, F045, F046, F047, F048, F049, F050, F051, F052)

PRODUCTS PRODUCED BY THE COMPANY LUIGI SALVADORI S.p.A., IN COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS REFERRED TO IN ANNEX I OF DIRECTIVE 93/42/EEC, AS AMENDED IN ITALY BY D. LGS. no. 37 OF 25/01/10 AS PROVIDED FOR BY ANNEX VII OF SUCH DIRECTIVE 93/42/EEC.

The undersigned Firm LUIGI SALVADORI S.r.l., located in Lodi (LO), Via G. Haussmann, 11/I, manufacturer of the above devices,

“Declares under its own responsibility that the devices referred to above meet all applicable provisions from Directive 93/42/EEC and Art. 120 (3) of Regulation (EU) 2017/745, on medical devices.”

To this end, the writer warrants and declares under his own responsibility the following:

- The subject devices meet the essential requirements as required by Annex I of Directive 93/42CEE;
- The subject devices are to be considered as belonging to Class [IIa];
- The subject devices are marketed in [sterile] packaging;
- The device production quality system complies with the essential requirements of Legislative Decree No. 37 of 25/01/10, as certified by Notified Body 0373, based on Annex V of the said Decree; CE Certificate Number: QPZ-1938-20
- The devices in question ARE NOT A MEASUREMENT INSTRUMENT;
- The subject devices ARE NOT INTENDED FOR CLINICAL INVESTIGATIONS;
- The manufacturer undertakes to establish a procedure for evaluation of experience gained, as prescribed in Annex VII, item 4, of the aforementioned Directive;
- The manufacturer undertakes to keep and make available to the Notified Body, the technical documentation specified in Annex VII of Directive 93/42/EEC for a period of ten years from the last date of manufacture of the product.

Therefore, it is hereby declared that these devices comply with the requirements of Directive 93/42/EEC and will be placed on the market with the CE marking in accordance with the provisions of Article 17 of Directive 93/42/EEC.

Lodi (Lo), there



GENERAL DIRECTION

Dr. Stefano Conti

Ditta Luigi Salvadori S.r.l.

A company of STS Medical Group S.à.r.l. - Società a responsabilità limitata soggetta a coordinamento e controllo di STS Medical Group S.à.r.l.

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