

DECLARATION OF CONFORMITY

We undersigned SOLTEC S.R.L., with head office addressed in MILANO, Via G. Röntgen 16 – 20136, and manufacturing plant in MILANO, Via Castelbarco 17 – 20136, declare under its own responsibility that the medical devices:

- **SONICA® S.A.M. 3 Basic – Automatic Multifunction System**
- **Ultrasonic baths SONICA® 1200 - SONICA® 2200 - SONICA® 2400 - SONICA® 3200 - SONICA® 3200L - SONICA® 3300 - SONICA® 4200 - SONICA® 4300 - SONICA® 5200 - SONICA® 5300 - SONICA® 45L - SONICA® 60L - SONICA® ATC67L - SONICA® 90L - Versions: M, MD, MH, MH D, ETH, EP, iETH, iEP**

risk class I, according to rule 12 to the Directive 93/42/EEC and further amendments, Annex IX (enforced in Italy by Legislative Decree No. 46/1997 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy by Legislative Decree No. 37/10):

- comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as the Technical File no. FT 002 ST retained by the Company;
- are manufactured according to the Quality System which satisfies requirements of Annex VII of the above mentioned Decree
- comply with Directive 2011 /65 / EU of the European Parliament and of the Council of 8 June 2011 about the restriction of the use of certain hazardous substances in electrical and electronic equipment.



Milano, 06th May 2015

SOLTEC S.R.L.

Chief Project Manager

Pietro Angelo Falbo

A handwritten signature in black ink, appearing to read 'Pietro Angelo Falbo', is written over a light blue horizontal line.