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 L**", risk class IIb, according to rule 15 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 001 ST retained by the Company;
- are manufactured according to the Quality System which satisfies requirements of Annex II without point 4 of the above mentioned Decree, as per CE Certificates No.: MED 31044, issued on 22nd May 2013 by the Notified Body No. 0476, KIWA CERMET ITALIA S.p.A.
- 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.

CE

Milano, 06th May 2015

SOLTEC S.R.L.
Chief Project Manager
Pietro Angelo Falbo