EU DECLARATION OF CONFORMITY

We undersigned SOLTEC S.r.l., single registration number (SRN): IT-MF-000018179
with recorded office addressed in MILANO, Via G. Röntgen 16 – 20136, as manufacturer of medical devices:

Product name	Codes	Basic UDI-DI
Sonica® S.A.M. 3 Basic	090.024.0001	805108418FT002ST2M
Sonica® S.A.M.3 BASIC USB 18LT	090.024.0004	805108418FT002ST2M
Sonica® S.A.M.3 BASIC USB	090.024.0003	805108418FT002ST2M
Sonica® TRENDMATIC 9 LT	090.024.0005	805108418FT002ST2M
Sonica® TRENDMATIC 18 LT	090.024.0006	805108418FT002ST2M

intended for cleaning, rinsing and drying surgical instruments, risk class I (Not Sterile), according to the rule 13 of the EU Regulation 2017/745, Annex VIII, declare under its own responsibility that the medical devices:

- comply with safety and performance requirements and dispositions of the EU Regulation 2017/745 and further amendments as per technical file kept on the premises of the company;
- no common specifications were used for the compliance of the aforementioned medical devices;
- comply with Directive 2011 /65 / EU and Directice RoHS III 2015/863/UE about the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- are manufactured according to the Quality System which satisfies requirements of Annex II + III of the above mentioned Regulation;
- comply with following standards: EN 61326-1:2013, EN 61010-1:2010, EN 61010-2-040:2015

Milan, date 03rd January 2022

SOLTEC S.r.l.
The CTO
[Chief Technical Officer]
Pietro Angelo Falbo