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 Ultrasonic Cleaner	1200MS3ZZVW	805108418FT002ST2M
	2200X(X(X)YYZZVW	
	2400X(X(X)YYZZVW	
	3200X(X(X(X)YYZZVW	
	3200LX(X)(X)(X)YYZZVW	
	3300X(X)(X)(X)YYZZVW	
	4200X(X)(X)(X)YYZZVW	
	4300X(X)(X)(X)YYZZVW	
	5200X(X)(X)(X)YYZZVW	
	5300X(X)(X)(X)YYZZVW	
	45XX(X)YYZZVW	
	60XX(X)YYZZVW	
	90XX(X)YYZZVW	
	ATXX(X)YYZZVW	

intended for cleaning of 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,

Milan, date 03rd January 2022

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