DECLARATION OF CONFORMITY

FAST ASSEMBLER S.r.l. Via San Domenico, 11/13- 20008 Bareggio (MI) – Legal Office: P.le Cadorna,13 20123 Milano - ITALY
family manufacturer of medical devices referred to

GLASS BEADS STERILIZERS

Models: " SIRIO MAXI", "SIRIO MAXI T " " GIMA QUICK , GIMA QUICK PLUS 240 "

Code Article: P-104046 / P-104047

As per the following references

FAST ASSEMBLER S.R.L.		GIMA S.P.A.	
REF	MODELLO	REF	MODELLO
P-104046	SIRIO MAXI	35640	GIMA QUICK
P-104047	SIRIO MAXI T	35642	GIMA QUICK PLUS 240

Serial Number:

for the hot air sterilization of medical devices, invasive too

declare under our own responsibility that devices meet all the essential requirements of Annex I to Directive 93/42/EEC, as amended by Directive 2007/47/EC, regarding Medical Devices.

To this purpose, ensures and declares under its own responsibility:

1. that the devices concerned meet the provisions of Directive 93/42/EEC, as amended, incorporated into national D.Lgs.n.46/97, as amended;
2. that the devices in question are the Class IIB under Rule 15 of Annex IX - Dir.93/42/CEE (intended to sterilize invasive devices, too);
3. that the devices in question are sold in NOT STERILE packaging.
4. who agrees to maintain and make available to the Notified Office the technical file of the product specified in point 3, Annex II of the Directive on Medical Devices, for a period of at least five years after the last product has been manufactured;
5. that the devices do not include derivatives of human blood or animal, nor phthalates;
6. that the devices meet the requirements of technical standard; CEI EN 61010-1 & IEC 61010-2-40
7. that the devices referred to the object are manufactured and marketed under the date of first entry and lot number (s/n), as indicated in the technical documentation of EC DECLARATION OF CONFORMITY '(Quality Management System) approved by the notified body ICIM SpA of Milan, identification number 0425 in accordance with Directive 93/42/EEC, with certificate nr. 0425-MED -002194-02 of 26.05.2024 as required by Annex II of this Directive;
8. that the manufacturer has established a systematic procedure to review experience gained from devices in the post-production phase, on the basis of the provisions set out in Annex X, as well as the evaluation of feedback from the market;
9. that the Quality System is certified according to UNI CEI EN ISO 13485:2016.

It was also stated that the Medical Devices comply with the requirements of the Directive on Low Voltage Directive 2014/35/UE

The manufacturer also declares that it has established and maintain appropriate procedures to ensure the post-marketing surveillance required by Directive 93/42/EEC.

RIVA Giampiero
Ceo

Date: Bareggio, 01 december 2020

Signature: _____