STS MEDICAL GROUP
IMPROVING HEALTHCARE THROUGH EFFICIENCY

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES:

- **MEDICAL DEVICES - STERILE;**

Code : 500-836	**Lot №: XXXXXXXXX**	**PL №: XXX**
Code : 625105K	**Lot №: XXXXXXXXX**	**PL №: XXX**
Code : 625106L	**Lot №: XXXXXXXXX**	**PL №: XXX**

PRODUCED FROM STS MEDICAL GROUP AD IN KEEPING WITH ESSENTIAL REQUIREMENTS ACCORDING TO ANNEX 1 OF DIRECTIVE 93/42/EEC – 2007/47/EC AS IS PROVIDED BY ANNEX VII FROM THE ABOVE-MENTIONED DIRECTIVE.

- The undersigned company STS MEDICAL GROUP AD – head office in Sandanski, Industrial area "Sokolovetz", producer of above mentioned devices,

"We declare that the above mentioned devices satisfy all orders applied with Directive 93/42/EEC -2007/47/EC regarding medical devices"

For this purpose the Undersigned Company guarantees and declares on own responsibility the following:

- The above mentioned device satisfies the essential requirements according to Annex 1 of Directive 93/42/EEC – 2007/47/EC;
- The device must be considered as belonging to Class IIa;
- The device is sold in packing STERILE;
- The sterilization is made with Ethylene oxide in STS MEDICAL GROUP AD with head office in 2800 Sandanski (Bulgaria);
- The sterilization is made according to the Quality system which is checked by Notified body №0373 – High Medicine Institute in Rome according to the requirements of Annex V, items 3 and 4 from Directive 93/42/EEC – 2007/47/EC;
- The system for quality of device's production conforms on essential requirements of Directive 93/42/EEC – 2007/47/EC, clear from certificate of Notified body №0373 – High Medicine Institute – Rome based on Annex V of above mentioned Directive;
- The device IS NOT A MEASUREMENT INSTRUMENT;
- The device IS NOT INTENDED FOR CLINICAL INVESTIGATIONS;
- The producer is obliged to make a procedure for evaluation of gained experience according to the provided in Annex VII, item 4 from the above mentioned Directive;
- The producer is obliged to keep the technical documents specified in Annex VII of Directive 93/42/EEC – 2007/47/EC in term of 5 years after the last date of production of the device and to place these documents at Competent authorities disposal.

It is declared that the Device conforms on ordered in Directive 93/42/EEC – 2007/47/EC and it will be put on the market with label "CE" according to the instruction of item 17 from Directive 93/42/EEC -2007/47/EC.

.In case of problem with some of the devices, please send an information on *dkassir@stsmedicalgroup.com*

Sandanski: 16.02.2023

Sign/...../
Denis Kassir
Quality Director and RA

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