EU DECLARATION OF CONFORMITY

Spes Medica S.r.l.

Certificated: EN ISO 13485:2016 Medical devices – Quality management system – system requirements for regulatory purposes.

Single Registration Number (SRN): IT-MF-000008858

Declares under its responsibility that the devices:

ECG Electrodes and accessories

BASIC UDI-DI: 8054655000019YB
Risk class: I, Rule I
Conformity Assessment Route: Annex IV
Intended use: Electrodes to be used for elctrobiological signal recording of cardiac muscle.

2.000041	KIT 6xSUAG0024, 1xCLAG000M, 1x50gr ECG-GEL
2.000052	KIT 6xSUAG0015,1xCLAGP00M, 1x50gr ECG-GEL
CLAG000M	Clamp electrode for ECG, in Ag/AgCl 1 PK= 4 PCS (green,yellow,red,black)
SUAG0024/6	Silver plated/silver chloride 24mm diam.suction chest elect- PK=6PCS

Fulfil the general safety and performance requirements of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

In addition, each of the listed medical device is manufactured from a Company with Quality System in conformity to UNI EN ISO 13485:2016 certified with registration number 0830.2020 dated 21.10.2005 by IMQ (0051), Via Quintiliano 43 - 20138 Milan - Italy.

Giuseppe Mafrici

CEO

Genova, 14/01/2022