EC 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:

Gel and Creams

BASIC UDI-DI: 8054655000012XV
Risk class: I, Rule I
Conformity Assessment Route: Annex IV
Intended use: Creams or gels to be used with surface electrodes to reduce the impedance and improve the conduction between the electrode surface and the skin.

EVERI160SPE-24	Skin prep cream,160gr tube BX = 24 PCS
NEURGEL250F	Conductive gel for EEG EP EMG 1 bottle of 250gr
SAC2-10	Adhesive and Conductive Electrode Cream tube 100gr - BX = 10 PCS

Fulfil the essentials 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, 14/07/2021