

Declaration CEen01-036

Mogliano Veneto, 6 May 2021

EC DECLARATION OF CONFORMITY

(According to Annex II of Directive 93/42/EEC and subsequent amendments and additions)

Micromed S.p.A.
Via Giotto, 2
I-31021 Mogliano Veneto (TV)

registered in Treviso no. TV03906850262, VAT number IT03906850262

DECLARES the following:

1. Micromed medical electrical devices listed in the following (the “products”) satisfy the Essential Requirements (Annex I) of the Directive 93/42/EEC and subsequent amendments and additions;
2. The Products are class IIb devices as indicated, according to the Annex IX classification rules of the Directive 93/42/EEC and subsequent amendments and additions;
3. The products comply with the safety requirements of the standards EN 60601-1:2006 + A1:2013, with EN 60601-1-2:2007 (or EN 60601-1-2:2015) and with EN 60601-2-26:2015 and EN 60601-2-40:2019 where applicable;
4. The products and systems are designed and manufactured within the Micromed Quality System, compliant with ISO 13485:2016 standard (certificate n. 9124.MIC4 issued by CSQ) and approved by IMQ Notified Body number 0051;
5. Each change to the products will be performed within the Quality System and according to the previously written Requirements;
6. All the corrective actions suggested from the experience on the devices in the post-production phase will be undertaken.
7. All the Quality Records referred to the products will be kept at least 5 years after the manufacture of the last product.
8. All the products are manufactured in our laboratories in accordance with the provisions of D.lgs. April 9, 2008, no. 81 and following modifications and additions.

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BRAIN QUICK®

MOBERG

NEUROWERK®

MYOQUICK®

SleepRT®

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REA n.307680

Capitale sociale 1.000.000,00€
Iscr. Reg. AEE IT08020000000841



Class IIb

- Electromyography and evoked response digital acquisition systems and review stations: MYOQUICK
- Electroencephalography and evoked response digital acquisition systems and review stations: BRAIN QUICK
- Stimulators for electromyography and evoked potentials: ENERGY; ENERGY TWIN; ENERGY LIGHT; ENERGY STIM
- Devices for acquisition of electromyographic and evoked potentials signals: MATRIX 1005; MATRIX 1009; MATRIX 1013; MATRIX 1017
- Combined devices for stimulation and acquisition of electromyographic and evoked potentials signals: MATRIX LIGHT; MATRIX EP LIGHT
- Electrophysiological signals acquisition and processing software: SystemPlus EVOLUTION; BRAIN QUICK SOFTWARE
- Electrical stimulators for electroencephalography: SD LTM STIM
- Devices for acquisition of Electroencephalographic and evoked potentials signals: SD LTM 32 EXPRESS, SD LTM 64 EXPRESS, SD PLUS RESEARCH, SD PLUS FLEXI, SD PLUS FLEXI HIGHRATE, SD PLUS FLEXI CLINIC, SD LTM 32 PLUS, SD LTM 64 PLUS
- Polygraph recorders: MORPHEUS, MORPHEUS LIGHT, BRAIN SPY PLUS

MICROMED S.p.A.
CEO
Cristiano Rizzo

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