



EC CERTIFICATE

Certificate No 1286/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

MICROMED SPA

31021 MOGLIANO VENETO (TV) - VIA GIOTTO 2 (ITA) - Italy

manages in the factory of:

31021 MOGLIANO VENETO (TV) - VIA GIOTTO 2 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Electrophysiological signals acquisition and processing software

Stimulators for electromyography and evoked potentials

Combined devices for stimulation and acquisition of electromyographic and evoked potentials signals

Devices for acquisition of electromyographic and evoked potentials signals

Electromyography and evoked response digital acquisition systems and review stations

Devices for acquisition of Electroencephalographic and evoked potentials signals

Electrical stimulators for electroencephalography

Portable recorders for polygraphy

Electroencephalography and evoked response digital acquisition systems and review stations

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AJ00282; 10AK00267; DM15E0502724-01; DM16-0005953-01; DM17-0011865-02; DM19-0039784-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2010-01-19
 Updated: 2019-11-06
 Substitution Date: 2017-10-20
 Expiry Date: 2024-05-26



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Annex

Electrophysiological signals acquisition and processing software

Stimulators for electromyography and evoked potentials

Combined devices for stimulation and acquisition of electromyographic and evoked potentials signals

Devices for acquisition of electromyographic and evoked potentials signals

Electromyography and evoked response digital acquisition systems and review stations

Devices for acquisition of Electroencephalographic and evoked potentials signals

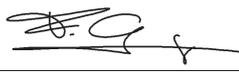
Electrical stimulators for electroencephalography

Portable recorders for polygraphy

Electroencephalography and evoked response digital acquisition systems and review stations

Type ref. as to document "EC Certificate Annex - Devices List" rev. 1 dated 2019/08/06; valid only if provided with IMQ stamp.

Date: 2010-01-19
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Allegato al Certificato CE - Elenco Dispositivi
EC Certificate Annex - Devices List

rev. 1 del 06/08/2019
rev. 1 dated 2019/08/06

Marca Trade mark:	Micromed
Categoria di prodotto: Product category:	Stimolatori per elettromiografia e potenziali evocati Stimulators for electromyography and evoked potentials
Modello: Type ref:	ENERGY; ENERGY TWIN; ENERGY LIGHT; ENERGY STIM
Categoria di prodotto: Product category:	Dispositivi per acquisizione di segnali elettromiografici e potenziali evocati Devices for acquisition of electromyographic and evoked potentials signals
Modello: Type ref:	MATRIX 1005; MATRIX 1009; MATRIX 1013; MATRIX 1017
Categoria di prodotto: Product category:	Dispositivi combinati per stimolazione e acquisizione di segnali elettromiografici e potenziali evocati Combined devices for stimulation and acquisition of electromyographic and evoked potentials signals
Modello: Type ref:	MATRIX LIGHT; MATRIX EP LIGHT
Categoria di prodotto: Product category:	Software per acquisizione ed elaborazione segnali elettrofisiologici Electrophysiological signals acquisition and processing software
Modello: Type ref:	SystemPlus EVOLUTION; BRAIN QUICK SOFTWARE
Categoria di prodotto: Product category:	Stimolatori elettrici per elettroencefalografia Electrical stimulators for electroencephalography
Modello: Type ref:	SD LTM STIM
Categoria di prodotto: Product category:	Dispositivi per acquisizione di segnali elettroencefalografici e potenziali evocati Devices for acquisition of Electroencephalographic and evoked potentials signals
Modello: Type ref:	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
Categoria di prodotto: Product category:	Registratori portatili per poligrafia Portable recorders for polygraphy
Modello: Type ref:	MORPHEUS; MORPHEUS LIGHT; BRAIN SPY PLUS
Categoria di prodotto: Product category:	Sistemi digitali di acquisizione e refertazione per elettromiografia e potenziali evocati Electromyography and evoked response digital acquisition systems and review stations
Modello: Type ref:	MYOQUICK
Categoria di prodotto: Product category:	Sistemi digitali di acquisizione e refertazione per elettroencefalografia e potenziali evocati Electroencephalography and evoked response digital acquisition systems and review stations
Modello: Type ref:	BRAIN QUICK



2019-11-06