

# EC CERTIFICATE

Certificate No 075/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:

### EB NEURO SPA

50127 FIRENZE (FI) - VIA PIETRO FANFANI 97/A (ITA) - Italy

manages in the factories of:

37020 ARBIZZANO DI VALPOLICELLA (VR) - VIA BOLOGNA 1 (ITA) - Italy

37030 COLOGNOLA AI COLLI (VR) - VIALE DEL LAVORO 20 (ITA) - Italy

50127 FIRENZE (FI) - VIA PIETRO FANFANI 97/A (ITA) - Italy

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

**Lan adapter for bioelectrical signals amplification system**

**Accessories**

**Electroencephalographs and Evoked Potential Systems**

**Multipurpose Electromyographs and Evoked Potential,  
Electroencephalographs and Monitoring Systems**

**Software for Electroencephalographs, Electromyographs, Evoked Potential  
and Patient Monitoring Systems**

**Bioelectrical signals amplification Equipments**

**Flash Stimulator Equipments**

**Electroencephalographs Systems**

**Diagnostic Electrocardiographs Systems**

**Transcranial magnetic Stimulators Systems and related Coils**

**Brain Navigation Systems**

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.

Date: 1998-09-02  
Updated: 2018-04-10  
Substitution Date: 2017-07-05  
Expiry Date: 2022-07-04

  
IMQ cosign

 **IMQ**   
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano  
Via Quintiliano 43  
tel. + 39 0250731  
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

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Reference to IMQ files Nos:

DM17-0009843-01; DM17-0009895-01; DM17-0016711-01.

**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.**

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MOD. 1475A / 2

## Annex

### Lan adapter for bioelectrical signals amplification system

Type ref. BE NET.  
Trade mark EB Neuro

### Accessories

Type ref. Electrical Stimulation probe; Hand-Held Electrical Stimulator 2+; DSM.  
Trade mark EB Neuro

### Electroencephalographs and Evoked Potential Systems

Series: BE LIGHT Type ref. Mizar Light; BE Light PC Peripheral.  
Trade mark EB Neuro

Series: BE PLUS Type ref. MIZAR PLUS; BE PLUS PC PERIPHERAL.  
Trade mark EB Neuro

Series: BE Micro Type ref. BE Micro.  
Trade mark EB Neuro

Series: BE Light 22 Type ref. BE Light 22 PC Peripheral.  
Trade mark EB Neuro

Series: BE PLUS LTM Type ref. BE PLUS LTM System.  
Trade mark EB Neuro

### Multipurpose Electromyographs and Evoked Potential, Electroencephalographs and Monitoring Systems

Series: NeMus 2 Type ref. NeMus 2 - 600; NeMus 2 +; NeMus 2-700.  
Trade mark EB Neuro

Series: MYTO PLUS ADVANCE Type ref. MYTO PLUS 600; MYTO PLUS +; MYTO PLUS 700.  
Trade mark EB Neuro

Series: NeMus 1 Type ref. NeMus SYSTEM; NeMus PC PERIPHERAL.  
Trade mark EB Neuro

Series: MYTO PLUS Type ref. MYTO PLUS SYSTEM; MYTO PLUS PC PERIPHERAL.  
Trade mark EB Neuro

### Software for Electroencephalographs, Electromyographs, Evoked Potential and Patient Monitoring Systems

Type ref. RSA; Galileo NT Line; Galileo GASTRO Line.  
Trade mark EB Neuro

### Bioelectrical signals amplification Equipments

Type ref. BE PLUS PRO; BE PLUS; BE Light; BE Light 22; BE PLUS LTM;

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## Annex

### **Bioelectrical signals amplification Equipments**

MYTO PLUS; MYTO PLUS ADVANCE; NeMus 1; NeMus 2.  
Trade mark EB Neuro

### **Flash Stimulator Equipments**

Type ref. GOGGLES STIMULATOR II.  
Trade mark EB Neuro

### **Electroencephalographs Systems**

Type ref. Neurotravel LIGHT.  
Trade mark ATES Medica Device

### **Diagnostic Electrocardiographs Systems**

Type ref. EASY ECG.  
Trade mark ATES Medica Device

### **Transcranial magnetic Stimulators Systems and related Coils**

Type ref. STM9000.  
Trade mark ATES Medica Device

### **Brain Navigation Systems**

Type ref. NetBrain 9000 Neuronavigator.  
Trade mark ATES Medica Device

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