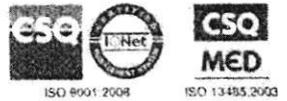




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**DICHIARAZIONE DI CONFORMITA' CE - DIRETTIVA 93/42/EEC
CE DECLARATION OF CONFORMITY - 93/42/EEC DIRECTIVE**

Costruttore/Manufacturer:

EB Neuro S.p.A.
Via P. Fanfani, 97/A
50127 - Firenze - Italia

Dispositivi Medici/Medical Devices:

Accessori per EEG (Cuffie, Elettrodi a coppetta, Elettrodi a ponte, Elettrodi Auricolari, Cavi)
EEG Accessories (Headcaps, Cup Electrodes, Bridge Electrodes, Auricular Electrodes, Cables)

Accessori per EMG (Elettrodi per registrazione e stimolazione, Elettrodi di superficie, Cavi)
EMG accessories (Stimulating and Recording Electrodes, Surface Electrodes, Cables)

Accessori per Cardiologia (Elettrodi, pinze)
Cardiology Accessories (Sensors)

Accessori per PSG (Trasduttori)
PSG Accessories (Sensors)

Codici identificativi/Reference codes:

Allegato 1 – Accessori Classe I Rev. C del 01/06/2014 / *Annex 1 – Class I Accessories Rev. B dated 2014/06/016*

Classificazione secondo direttiva 93/42/EEC e s.m.i. 2007/47/EC (D.Lgs. n° 46/97) /
Classification according to 93/42/EEC directive and its revised version 2007/47/EC (Italian law no. 46/97):

Classe I (Dispositivo Medico Non Sterile senza funzione di misura)
Class I (Not-Sterile without measuring function Medical Device)

Applicabilità marcatura CE/Applicability of CE marking:

Ai Dispositivi Medici (tutti i numeri di Lotto) immessi in commercio dopo la data del 16/01/2013
To Medical Devices (all Lot numbers) released on the market after the date of 16/01/2013

Il costruttore dichiara che i Dispositivi Medici, come sopra specificato e le relative opzioni, sono stati costruiti applicando il sistema di garanzia della qualità approvato per la progettazione, fabbricazione e controllo finale del prodotto e rispondono ai requisiti presenti nell'Allegato VII della Direttiva 93/42/EEC MDD (D.Lgs. n°46/97) per la Classe I (Regola 1); compresi, dal 21 marzo 2010, gli emendamenti della Direttiva 2007/47/EC (D.Lgs. n° 37/2010).

The manufacturer declares that the Medical Devices, as specified above and the related options, have been manufactured by applying the quality system approved for the design, manufacture and final inspection and meet the requirements of the 93/42/EEC - Annex VII (Italian law D.Lgs. no. 46/97) MDD for the Class I (Rule 1); including, at 21 March 2010, the amendments by Directive 2007/47/EC (Italian law D.Lgs. no. 37/2010).

**QUESTA DICHIARAZIONE SI BASA SUI SEGUENTI ELEMENTI:
THIS DECLARATION IS BASED ON THE FOLLOWING ITEMS:**

- Fascicolo Tecnico come da punto 3 dell'Allegato VII, a dimostrazione della conformità del prodotto, comprese tutte le varianti applicabili, di cui all'Allegato I (Requisiti Essenziali).
Technical Dossier as Annex VII – Section 3, for the demonstration of product conformity, including all the applicable configurations with reference to Annex I (Essential Requirements)
- Applicazione delle procedure descritte in Sezione 4, Allegato VII
Application of the procedures described in Annex VII – Section 4

Data emissione/Date of issue (Rev.C): 01/06/2014

Il legale rappresentante
Authorized officer
Marco Rossi




 KOLLEGIJA
 Apskaitės
 ir
 Audito
 tarnyba
 2022-07-25

 LIETUVOS RESPUBLIKA
 Sveikatos ir
 Socialinės apsaugos
 uždaroji akcinė
 bendrovė
 HOSPITEX DIAGNOSTICS
 KAUNAS
 KAUNO MIESTAS



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Allegato 1 / Annex 1 Accessori Classe I / Class I Accessories Rev. C del 01/06/2014 / Rev. C dated 2014/06/01	Pagina / Page 1/6
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Nome Modello / Model Name	Codice identificativo / Reference code
<i>Cuffia in Silicone Flessibile Regolabile 6X2 Piccola</i> Small Silicon Flexible Adjustable Headcap 6X2	B9720410001
<i>Cuffia in Silicone Flessibile Regolabile 6X2 Media</i> Medium Silicon Flexible Adjustable Headcap 6X2	B9720410002
<i>Cuffia in Silicone Flessibile Regolabile 6X2 Grande</i> Big Silicon Flexible Adjustable Headcap 6X2	B9720410003
<i>Cuffia in Silicone Flessibile Regolabile 6X4 Piccola</i> Small Silicon Flexible Adjustable Headcap 6X4	B9720410011
<i>Cuffia in Silicone Flessibile Regolabile 6X4 Media</i> Medium Silicon Flexible Adjustable Headcap 6X4	B9720410012
<i>Cuffia in Silicone Flessibile Regolabile 6X4 Grande</i> Big Silicon Flexible Adjustable Headcap 6X4	B9720410013
<i>Cuffia in PTS Flessibile Regolabile 4X1 Neonatale + Velcro, Blu</i> Neonatal PTS Flexible Adjustable Headcap 4X1 + Velcro, Blue	B9720440001
<i>Cuffia in PTS Flessibile Regolabile 6X2 Piccola + Velcro, Blu</i> Small PTS Flexible Adjustable Headcap 6X2 + Velcro, Blue	B9720440011
<i>Cuffia in PTS Flessibile Regolabile 6X2 Media + Velcro, Verde</i> Medium PTS Flexible Adjustable Headcap 6X2 + Velcro, Green	B9720440012
<i>Cuffia in PTS Flessibile Regolabile 6X2 Grande + Velcro, Rossa</i> Large PTS Flexible Adjustable Headcap 6X2 + Velcro, Red	B9720440013
<i>Cuffia in PTS Flessibile Regolabile 6X4 Piccola + Velcro, Blu</i> Small PTS Flexible Adjustable Headcap 6X4 + Velcro, Blue	B9720440021
<i>Cuffia in PTS Flessibile Regolabile 6X4 Media + Velcro, Verde</i> Medium PTS Flexible Adjustable Headcap 6X4 + Velcro, Green	B9720440022
<i>Cuffia in PTS Flessibile Regolabile 6X4 Grande + Velcro, Rossa</i> Large PTS Flexible Adjustable Headcap 6X4 + Velcro, Red	B9720440023
<i>Cuffia EEG Standard 10 Elettrodi in Stagno (UNIVERSALE) - Misura 1</i> EEG Standard Headcap 10 Tin Electrodes (UNIVERSAL) - Size 1	B9720420101
<i>Cuffia EEG Standard 10 Elettrodi in Stagno (UNIVERSALE) - Misura 2</i> EEG Standard Headcap 10 Tin Electrodes (UNIVERSAL) - Size 2	B9720420102
<i>Cuffia EEG Standard 20 Elettrodi in Stagno (UNIVERSALE) - Misura 3</i> EEG Standard Headcap 20 Tin Electrodes (UNIVERSAL) - Size 3	B9720420103
<i>Cuffia EEG Standard 20 Elettrodi in Stagno (UNIVERSALE) - Misura 4</i> EEG Standard Headcap 20 Tin Electrodes (UNIVERSAL) - Size 4	B9720420104
<i>Cuffia EEG Standard 20 Elettrodi in Stagno (UNIVERSALE) - Misura 5</i> EEG Standard Headcap 20 Tin Electrodes (UNIVERSAL) - Size 5	B9720420105
<i>Cuffia EEG Standard 20 Elettrodi in Stagno (UNIVERSALE) - Misura 6</i> EEG Standard Headcap 20 Tin Electrodes (UNIVERSAL) - Size 6	B9720420106
<i>Cuffia EEG Standard 20 Elettrodi in Stagno (UNIVERSALE) - Misura 7</i> EEG Standard Headcap 20 Tin Electrodes (UNIVERSAL) - Size 7	B9720420107
<i>Elettrodi a Coppetta Standard Au, Diametro 10mm, Cavo 120cm, FMM 1,5mm</i> Standard Au Cup Electrode, Diameter 10mm, 120cm, FMM 1,5mm	B9720101001



KOJ IJA TURKA
Direktorius
Algis Bakalis

2022-07-25



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Allegato 1 / Annex 1

Accessori Classe I / Class I Accessories

Rev. C del 01/06/2014 / Rev. C dated 2014/06/01

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Nome Modello / Model Name	Codice identificativo / Reference code
Elettrodi a Coppetta Extreme Au, Diametro 10mm, Cavo 120cm, FMM 1,5mm Extreme Au Cup Electrode, Diameter 10mm, 120cm, FMM 1,5mm	B9720101002
Elettrodi a Coppetta Pediatrici Au, Diametro 6mm, Cavo 120cm, FMM 1,5mm Pediatric Au Cup Electrode, Diameter 6mm, 120cm, FMM 1,5mm	B9720101003
Elettrodi a Coppetta Standard Au, Diametro 10mm, Cavo 150cm, FMM 1,5mm Standard Au Cup Electrode, Diameter 10mm, 150cm, FMM 1,5mm	B9720101011
Elettrodi a Coppetta Extreme Au, Diametro 10mm, Cavo 150cm, FMM 1,5mm Extreme Au Cup Electrode, Diameter 10mm, 150cm, FMM 1,5mm	B9720101012
Elettrodi a Coppetta Pediatrici Au, Diametro 6mm, Cavo 150cm, FMM 1,5mm Pediatric Au Cup Electrode, Diameter 6mm, 150cm, FMM 1,5mm	B9720101013
Elettrodi a Coppetta Standard Ag/AgCl, Diametro 10mm, Cavo 120cm, FMM 1,5mm Standard Ag/AgCl Cup Electrode, Diameter 10mm, 120cm, FMM 1,5mm	B9720104001
Elettrodi a Coppetta Extreme Ag/AgCl, Diametro 10mm, Cavo 120cm, FMM 1,5mm Extreme Ag/AgCl Cup Electrode, Diameter 10mm, 120cm, FMM 1,5mm	B9720104002
Elettrodi a Coppetta Pediatrici Ag/AgCl, Diametro 6mm, Cavo 120cm, FMM 1,5mm Pediatric Ag/AgCl Cup Electrode, Diameter 6mm, 120cm, FMM 1,5mm	B9720104003
Elettrodi a Coppetta Standard Ag/AgCl, Diametro 10mm, Cavo 150cm, FMM 1,5mm Standard Ag/AgCl Cup Electrode, Diameter 10mm, 150cm, FMM 1,5mm	B9720104011
Elettrodi a Coppetta Extreme Ag/AgCl, Diametro 10mm, Cavo 150cm, FMM 1,5mm Extreme Ag/AgCl Cup Electrode, Diameter 10mm, 150cm, FMM 1,5mm	B9720104012
Elettrodi a Coppetta Pediatrici Ag/AgCl, Diametro 6mm, Cavo 150cm, FMM 1,5mm Pediatric Ag/AgCl Cup Electrode, Diameter 6mm, 150cm, FMM 1,5mm	B9720104013
Elettrodo a Ponte Au, Adulti, Colore Verde Bridge Electrode, Au, Adult, Green	B9720111001
Elettrodo a Ponte Au, Pediatrici, Colore Blu Bridge Electrode, Au, Pediatric, Blue	B9720111002
Elettrodo a Ponte Ag/AgCl, Adulti, Colore Verde Bridge Electrode, Ag/AgCl, Adult, Green	B9720114001
Elettrodo a Ponte Ag/AgCl, Pediatrici, Colore Blu Bridge Electrode, Ag/AgCl, Pediatric, Blue	B9720114002
Connection Cable for Bridge Electrode 120cm - 2mm Banana / FMM 1,5mm	B9720350001
Cavi Collegamento Elettrodo Ponte 120cm - Attacco Coccodrillo / FMM D=1,5mm Connection Cable for Bridge Electrode 120cm - Alligator Clip / FMM 1,5mm	B9720350002
Set Ricopertura per Elettrodi Ponte Toolkit for Bridge Electrodes	B9720070001
Cavo di Connessione 100cm Tuchel per Pin 0,7mm (Rosso/Nero) Connecting Cable Pin 0,7mm Tuchel 100cm (Red/Black)	B9720320001
Cavo di Connessione 200cm Tuchel per Pin 0,7mm (Rosso/Nero) Connecting Cable Pin 0,7mm Tuchel 200cm (Red/Black)	B9720320002
Cavo di Connessione 100cm Tuchel per Pin 0,7mm (Rosso/Nero/Verde) Connecting Cable Pin 0,7mm Tuchel 100cm (Red/Black/Green)	B9720320003
Cavo di Connessione 200cm Tuchel per Pin 0,7mm (Rosso/Nero/Verde)	B9720320004



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Allegato 1 / Annex 1 Accessori Classe I / Class I Accessories Rev. C del 01/06/2014 / Rev. C dated 2014/06/01	Pagina / Page 3/6
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Nome Modello / Model Name	Codice identificativo / Reference code
Connecting Cable Pin 0,7mm Tuchel 200cm (Red/Black/Green)	
Cavo di Connessione 100cm FMM 1,5mm per Pin 0,7mm (Rosso/Nero) Connecting Cable Pin 0,7mm FMM 1,5mm 100cm (Red/Black)	B9720320011
Cavo di Connessione 200cm FMM 1,5mm per Pin 0,7mm (Rosso/Nero) Connecting Cable Pin 0,7mm FMM 1,5mm 200cm (Red/Black)	B9720320012
Cavo di Connessione 100cm FMM 1,5mm per Pin 0,7mm (Rosso/Nero/Verde) Connecting Cable Pin 0,7mm FMM 1,5mm 100cm (Red/Black/Green)	B9720320013
Cavo di Connessione 200cm FMM 1,5mm per Pin 0,7mm (Rosso/Nero/Verde) Connecting Cable Pin 0,7mm FMM 1,5mm 200cm (Red/Black/Green)	B9720320014
Cavo di Connessione 120cm FMM 1mm / FMM 1,5mm (Differenti Colori) Connecting Cable 120cm FMM 1mm / FMM 1,5mm (Different Colors)	B9720320901
Cavo di Connessione 120cm MCH 1,5mm / FMM 1,5mm Connecting Cable 120cm MCH 1,5mm / FMM 1,5mm	B9720320902
Cavo di Connessione 120cm Pin 0,7mm FMM 1,5mm Connecting Cable Pin 0,7mm FMM 1,5mm 120cm	B9720320903
Cavo di Connessione 150cm FMM 1mm / FMM 1,5mm (Differenti Colori) Connecting Cable 150cm FMM 1mm / FMM 1,5mm (Different Colors)	B9720320911
Cavo di Connessione 150cm MCH 1,5mm / FMM 1,5mm Connecting Cable 150cm MCH 1,5mm / FMM 1,5mm	B9720320912
Cavo di Connessione 150cm Pin 0,7mm FMM 1,5mm Connecting Cable Pin 0,7mm FMM 1,5mm 150cm	B9720320913
Cavo di Connessione 120cm per Bottone e FMM 1,5mm – NERO SNAP Cable with 120cm Cable and FMM 1,5mm Connector - BLACK	B9720390901
Cavo di Connessione 120cm per Bottone e FMM 1,5mm – ROSSO SNAP Cable with 120cm Cable and FMM 1,5mm Connector - RED	B9720390902
Cavo di Connessione 120cm per Bottone e FMM 1,5mm – VERDE SNAP Cable with 120cm Cable and FMM 1,5mm Connector - GREEN	B9720390903
Cavo di Connessione 150cm per Bottone e FMM 1,5mm – NERO SNAP Cable with 150cm Cable and FMM 1,5mm Connector - BLACK	B9720390911
Cavo di Connessione 150cm per Bottone e FMM 1,5mm – ROSSO SNAP Cable with 150cm Cable and FMM 1,5mm Connector - RED	B9720390912
Cavo di Connessione 150cm per Bottone e FMM 1,5mm – VERDE SNAP Cable with 150cm Cable and FMM 1,5mm Connector - GREEN	B9720390913
Cavo di Connessione 200cm per Bottone e FMM 1,5mm – NERO SNAP Cable with 200cm Cable and FMM 1,5mm Connector - BLACK	B9720390921
Cavo di Connessione 200cm per Bottone e FMM 1,5mm – ROSSO SNAP Cable with 200cm Cable and FMM 1,5mm Connector - RED	B9720390922
Cavo di Connessione 200cm per Bottone e FMM 1,5mm – VERDE SNAP Cable with 200cm Cable and FMM 1,5mm Connector - GREEN	B9720390923
Adattatori Attacco 4mm Banana / Bottone Adapter Banana 4mm / Snap	B9720390990
Stimolatore Elettrico a Barra con Impugnatura, Acciaio Inox, FMM 1,5mm	B9720187001



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Allegato 1 / Annex 1 Accessori Classe I / Class I Accessories Rev. C del 01/06//2014 / Rev. C dated 2014/06/01	Pagina / Page 4/6
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Nome Modello / Model Name	Codice identificativo / Reference code
<i>Bar Stimulator with Handle, Inox, FMM 1,5mm</i>	
<i>Stimolatore Elettrico a Barra con Impugnatura, Acciaio Inox, Tuchel</i>	B9720187002
<i>Bar Stimulator with Handle, Inox, Tuchel</i>	
<i>Stimolatore Elettrico a Barra con Impugnatura, Feltri Circolari o Elettrodi in Acciaio, FMM 1,5mm</i>	B9720187003
<i>Bar Stimulator with Handle, Interchangeable Circular Felt / Inox Tips, FMM 1,5mm</i>	
<i>Stimolatore Elettrico a Barra con Impugnatura, Feltri Circolari o Elettrodi in Acciaio, Tuchel</i>	B9720187004
<i>Bar Stimulator with Handle, Interchangeable Circular Felt / Inox Tips, Tuchel</i>	
<i>Feltri di Ricambio per Stimolatore a barra</i>	B9720070002
<i>Exchange Circular Felt Tips for Bar Stimulator</i>	
<i>Elettrodi in Acciaio di Ricambio per Stimolatore a barra</i>	B9720197001
<i>Exchange Circular Inox Tips for Bar Stimulator</i>	
<i>Trasduttore Russamento FMM 1,5mm Cavo 200cm</i>	B9720700001
<i>Snoring Sensor with 200cm Cable and FMM 1,5mm Connector</i>	
<i>Trasduttore Respiro Toracico Adulto FMM 1,5mm Cavo 200cm con Fasce Elastiche 100cm e 150cm</i>	B9720710001
<i>Adult Thoracic and Abdomen Belts with 200cm Cable and FMM 1,5mm Connector, with Elastic Belts 100cm and 150cm</i>	
<i>Trasduttore Respiro Toracico Pediatrico FMM 1,5mm Cavo 200cm con Fasce Elastiche 50cm e 70cm</i>	B9720710002
<i>Pediatric Thoracic and Abdomen Belts with 200cm Cable and FMM 1,5mm Connector, with Elastic Belts 50cm and 70cm</i>	
<i>Trasduttore piezoelettrico per respiro adesivo monouso Adulto FMM 1,5mm Cavo 200cm</i>	B9720710003
<i>Adult Disposable Adesive Piezoelectric Breath Transducer 200cm Cable and FMM 1,5mm</i>	
<i>Trasduttore piezoelettrico per respiro adesivo monouso Pediatrico FMM 1,5mm Cavo 200cm</i>	B9720710004
<i>Pediatric Disposable Adesive Piezoelectric Breath Transducer 200cm Cable and FMM 1,5mm</i>	
<i>Trasduttore Termocoppia 3 Vie Adulti FMM 1,5mm Cavo 200cm</i>	B9720720001
<i>Adult 3 Way Thermocouple with 200cm Cable and FMM 1,5mm Connector</i>	
<i>Trasduttore Termocoppia 3 Vie Pediatrico FMM 1,5mm Cavo 200cm</i>	B9720720002
<i>Pediatric 3 Way Thermocouple with 200cm Cable and FMM 1,5mm Connector</i>	
<i>Trasduttore Movimento Articolare FMM 1,5mm Cavo 200cm</i>	B9720730001
<i>Limb Transducer with 200cm Cable and FMM 1,5mm Connector</i>	
<i>Trasduttore Tremore Muscolare FMM 1,5mm Cavo 200cm</i>	B9720730002
<i>Tremor Sensor with 200cm Cable and FMM 1,5mm Connector</i>	
<i>Modulo d'interfaccia per trasduttore piezoelettrico di respiro</i>	B9720790001
<i>Interface module for piezoelectric breath transducer</i>	
<i>Stimolatore Elettrico ad Anello in Tessuto Conduttivo, FMM 1,5mm</i>	B9720550001
<i>Conductive Tissue Ring Stimulator, Not-Elastic, FMM 1,5mm</i>	
<i>Stimolatore Elettrico ad Anello in Tessuto Conduttivo, Tuchel</i>	B9720550002
<i>Conductive Tissue Ring Stimulator, Not-Elastic, Tuchel</i>	
<i>Stimolatore Elettrico ad Anello in Molla Acciaio, FMM 1,5mm</i>	B9720550011
<i>Steel Ring Stimulator, Not-Elastic, FMM 1,5mm</i>	



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Le progrès, une passion à partager

Certification
Médical-Santé

Notified Body N° 0459

[Handwritten signature]

K. ANTKE
Direktoriaus
V. Bakutis



ATTESTATION / CERTIFICATE N° 7679 rev. 7

Délivrée à Paris le 22 mars 2016

Issued in Paris on March 22nd, 2016

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

MEDIPREMA

470 rue Gilles de Gennes Zone d'Activité Node Park Touraine

37310 TAUXIGNY FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Dispositifs médicaux pour la néonatalogie, périnatalogie et pédiatrie.

Medical devices for neonatology, perinatology and pediatrics.

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P145398, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P145398, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification



On behalf of the Certification Director

Cécile VAUGELADE

G-MED Certification Division Manager

LNE - 7679 rev. 7

Renouvelle le certificat 7679-8

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial

LNE/G-MED • Organisme notifié n° 0459

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0459_7679-02-25-2016