

QUALITY FOR...



BIONEN
medical devices



EEG ELECTRODES

Electroencephalography (EEG) is the recording of electrical activity along the scalp. In clinical contexts, EEG refers to the recording of the brain's spontaneous electrical activity over a short period of time, (20–40 minutes), as recorded from multiple electrodes placed on the scalp.

Electrodes are placed with a conductive gel or paste, after preparing the scalp area by light abrasion to reduce impedance due to dead skin cells.

Many systems typically use electrodes attached to an individual wire, some systems use caps or nets into which electrodes are embedded.

Electrode locations and names are specified by the 10–20 International System to ensure that the naming of electrodes is consistent across laboratories.

An EEG can determine changes in brain activity that may be useful in diagnosing brain disorders, especially epilepsy. An EEG may be helpful for diagnosing or treating a variety of physical disorders:

- Epilepsy or other seizure disorders
- Brain tumor
- Head injury
- Brain dysfunction (i.e. encephalopathy)
- Inflammation of the brain (encephalitis)
- Stroke
- Sleep disorders
- Dementia

An EEG may also be used to confirm brain death in someone in a persistent coma. A continuous EEG is used to help find the right level of anesthesia for someone in a medically induced coma.

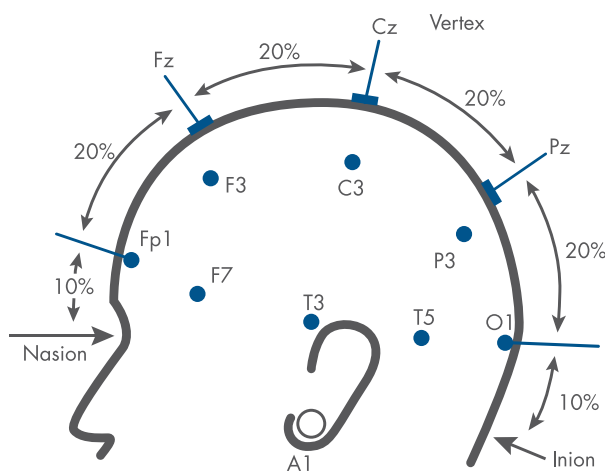
EEGs are safe and painless. Sometimes seizures are intentionally triggered in people with epilepsy during the test, but appropriate medical care is provided if needed.

10-20 INTERNATIONAL SYSTEM (EEG)

EEG electrodes are placed on the scalp according a recognized method to correctly localize the electrode positioning. This method was developed to ensure standardized reproducibility so that a subject's studies could be compared over time and subjects could be compared to each other.

The 10–20 International System is based on the relationship between the location of an electrode and the underlying area of cerebral cortex. The "10" and "20" refer to the fact that the actual distances between adjacent electrodes are either 10% or 20% of the total front–back or right–left distance of the skull. Each site has a letter to identify the lobe and a number to identify the hemisphere location.

ELECTRODE	LOBE
F	Frontal
T	Temporal
C	Central
P	Parietal
O	Occipital



There exists no central lobe; the "C" letter is used only for identification purposes.

A "z" (zero) refers to an electrode placed on the midline.

Even numbers (2,4,6,8) refer to electrode positions on the right hemisphere, whereas odd numbers (1,3,5,7) refer to those on the left hemisphere.

In addition, the letter codes A, Pg and Fp identify the earlobes, nasopharyngeal and frontal polar sites respectively.

Four anatomical landmarks are used for the essential positioning of the EEG electrodes: first, the nasion which is the distinctly depressed area between the eyes, just above the bridge of the nose; second, the inion, which is the lowest point of the skull from the back of the head and is normally indicated by a prominent bump. Then the pre auricular points anterior to the ear.

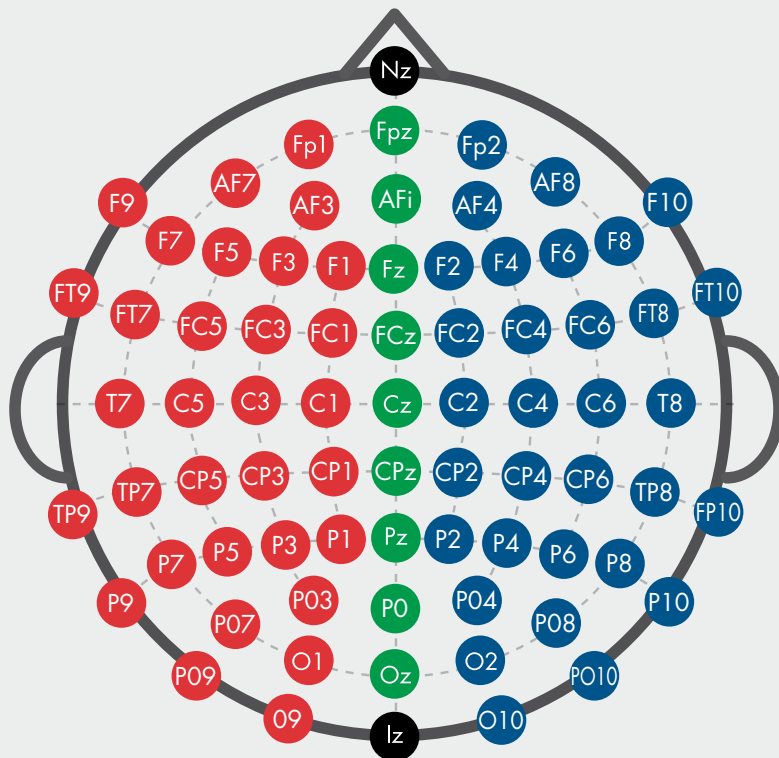
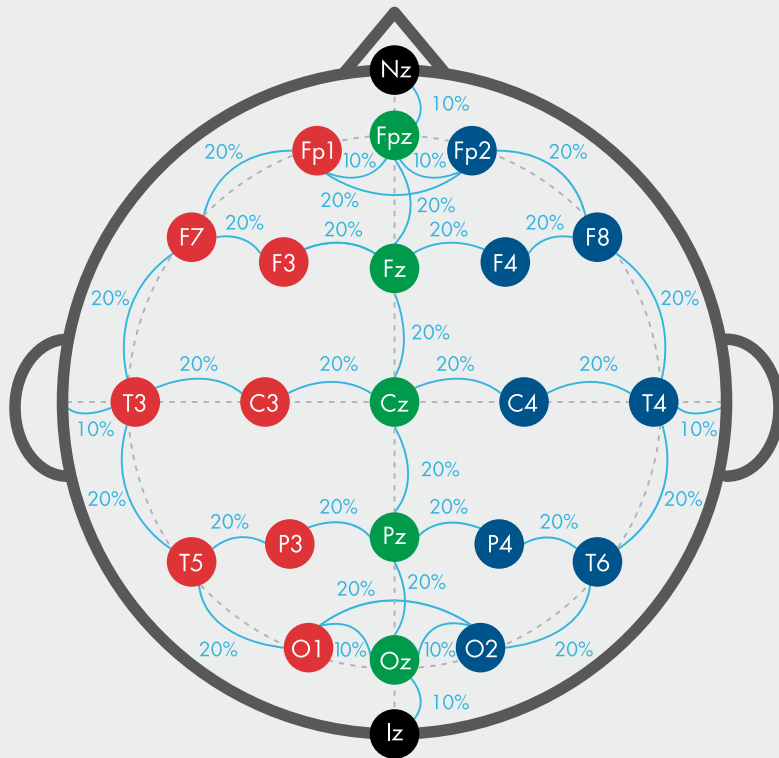
With the advent of multi-channel EEG hardware systems and the concurrent development of topographic and tomographic signal source localization methods, the international 10/20 system was extended to higher density electrode settings such as 10/10 and 10/5 systems, allowing more than 300 electrode positions.

In most clinical applications, 19 recording electrodes (plus ground and system reference) are used.

A smaller number of electrodes are typically used when recording EEG from neonates (usually 10). Additional electrodes can be added to the standard set-up when a clinical or research application demands increased spatial resolution for a particular area of the brain.

High-density arrays can contain up to 256 electrodes spaced around the scalp.

BIONEN can develop custom headcaps for your specific requirements.



PREWIRED HEADCAPS

Electrodes are positioned according to the 10-20 International System embedded on an elastic cap perfectly fitting on the head.

Headcap is simple and fast to place and guarantees the stability of the electrodes.

This system guarantees a drastic reduction of exam's preparation time and costs.

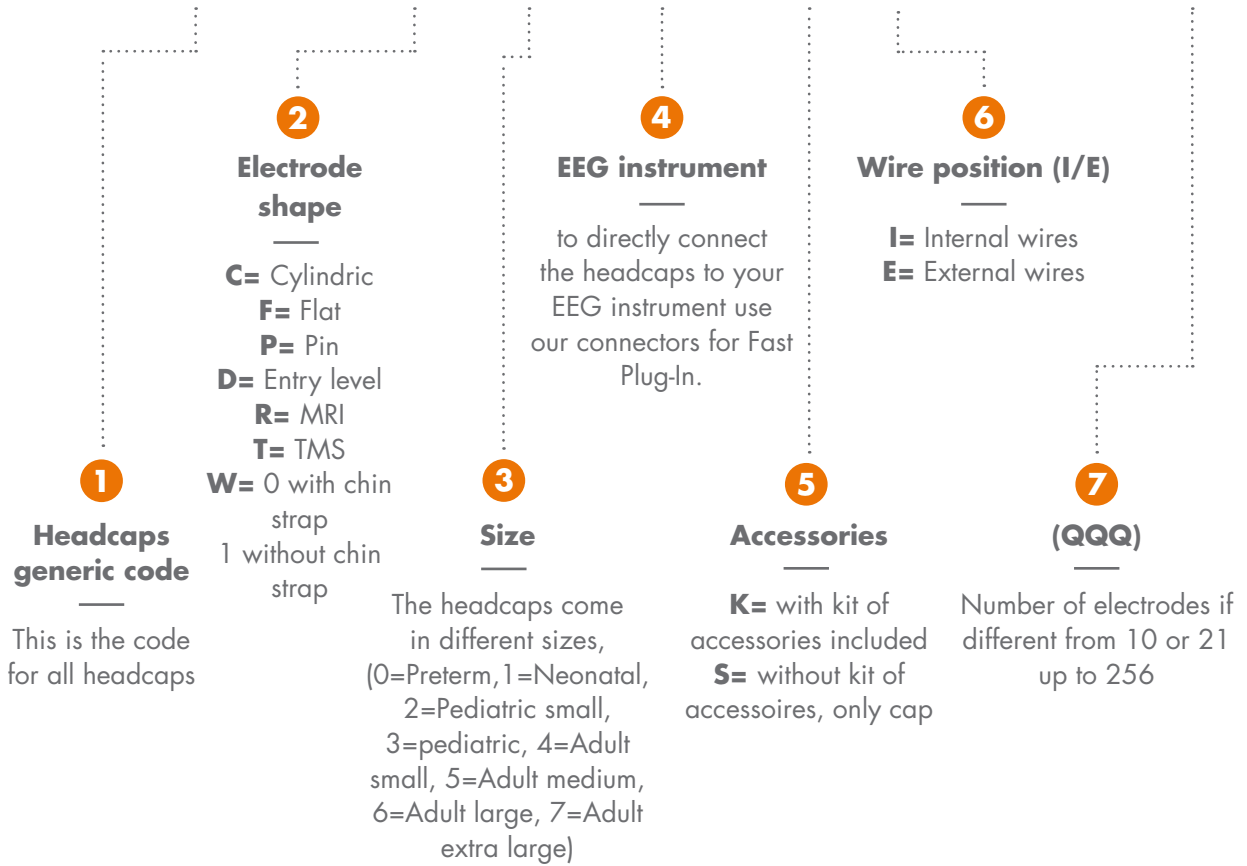
Our headcaps can be customized for electrodes' number and montages (10-20, 10-10, 10-5).

- Simple and fast to prepare
- Stable and correct placement of the electrodes
- Conductive paste insertion is simplified by the electrode's support hole
- Suitable for children and patients who need to reduce the preparation time
- Accessories' kit: thoracic belt, chin strap, elastic belts, syringe, blunted needle

INTENDED USE: **EEG**

BIONEN headcaps' range is wide and complete, to meet all customers' needs we have developed different solutions that are explained by the code itself:

0013.XWY-ZZZ-J-K-(QQQ)





SIZES & NUMBER OF ELECTRODES

8 color-coded sizes (2 neonatal, 2 pediatrics, 4 adults) are available for every model.

SIZE CODE EXAMPLE: 0013. XX **X** - XXX - X - X

REF	SIZE	PATIENT	HEAD CIRCUMFERENCE	AVAILABLE ELECTRODES #					
				10	21	32	64	128	256
0013.XX0	0	preterm	25 ± 2 cm	●	●				
0013.XX1	1	neonatal	30 ± 2 cm	●	●				
0013.XX2	2	pediatric small	35 ± 2 cm	●	●				
0013.XX3	3	pediatric	40 ± 2 cm	●	●	●			
0013.XX4	4	adult small	45 ± 2 cm	●	●	●	●		
0013.XX5	5	adult medium	50 ± 2 cm	●	●	●	●	●	●
0013.XX6	6	adult large	55 ± 2 cm	●	●	●	●	●	●
0013.XX7	7	adult extra large	60 ± 2 cm	●	●	●	●	●	●



FABRIC PERFORMANCES

Breathable, extremely light, the unique ultra-thin fabric with 27% LYCRA® and soft microfiber with unique performances. More comfortable fabric for the patient and easier maintenance for the operator.



Extra comfort

Offers great wearability and perfect shape even after repeated washing.



Breathability

Provides perfect breathability and greater freshness. These qualities make it cooler and more hygienic.



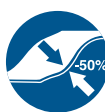
Extra resistant

more durable and resistant to the corrosive action of chlorine and protect it from the salt and corrosive agents in creams.



Quick drying

Dries twice as fast than other fabrics, quick and easy to maintain.



Extra fine

Supports with less bulk and superior softness.



Sensitivecosystem®

Commitment to Eco sustainability and the environment.

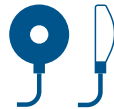
AVAILABLE ELECTRODES

All versions of BIONEN headcaps have Silver (Ag/AgCl) electrodes to guarantee reliable recording. Wires can be positioned outside or inside the fabric. Available electrodes' shapes are the following with different features:



CYLINDRIC ELECTRODES

0013.**CXx**



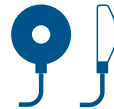
FLAT ELECTRODES

0013.**FXx**



PIN ELECTRODES

0013.**PXx**



ENTRY LEVEL ELECTRODES

0013.**DXx**



MRI ELECTRODES

0013.**RXx**

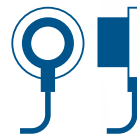


TMS ELECTRODES

0013.**TXx**

CYLINDRIC

CODE EXAMPLE 0013. **CXx** - XXX - X - X



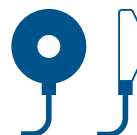
- Soft electrode holder to guarantee more patient comfort.
- Wider holes make paste insertion easier.
- Impedance reduction using a comfortable cotton swab.
- Simple maintenance and replacement of broken and emergency electrodes.



0013.**CXx** - XXX - X - **E**

FLAT

CODE EXAMPLE 0013. **FXx** - XXX - X - X



- Molded connection between electrode and wire avoid oxidation and increase the product life.
- Emergency electrodes available.



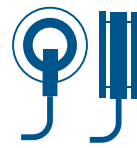
0013.**FXx** - XXX - X - **E**



PIN

CODE EXAMPLE 0013.**PXX-XXX-X - X**

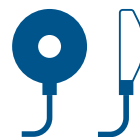
- Suggested for Long Term Monitoring (LTM) recordings, uncooperative patients
- Exclusive ultrathin electrode
- Internal wires, not in contact with the scalp



ENTRY LEVEL

CODE EXAMPLE 0013.**DXX-XXX-X - X**

- Suggested for a not intense use of prewired headcap in EEG recording
- Electrodes studied for a good impedance



EEG HEADCAPS FOR SPECIAL APPLICATIONS

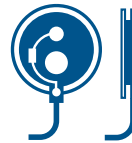


MRI

CODE EXAMPLE 0013.**ROX** - XXX - X - X

EEG-fMRI is a multimodal neuroimaging technique that allows to acquire EEG and fMRI data simultaneously. This technique is used to study brain activity in normal conditions and in presence of pathologies.

The EEG recorded on the surface of the head reflects the cerebral electrical activity, more specifically generated by post-synaptic potentials in the cerebral cortex.



Functional MRI detects hemodynamic changes throughout the brain. The EEG-fMRI therefore allows the direct correlation of these two important measures of brain activity.

The BIONEN MRI headcaps:

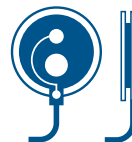
- are built with non-magnetic materials
- guarantee the safety of the subject by preserving the quality of functional and structural MR images.

TMS

CODE EXAMPLE 0013.**TOX** - XXX - X - X

TMS is a non-invasive technique for brain stimulation. The combination of stimulation techniques with electrophysiological recording methods in order to better understand human brain functioning is of great interest.

The co-registration of the EEG during magnetic stimulation offers real-time information on both the state of cortical activity and its functional connectivity.



From a technical point of view, EEG headcap during TMS must have a high dynamic range of acquisition in order not to saturate the signal and a reduced thickness of the EEG electrodes in order not to negatively influence the depth of action of the magnetic stimulus and not to be an obstacle to the positioning of the magnetic stimulation probe.



STAND-UP

CODE EXAMPLE

0013.**C1**X - XXX - X - X

0013.**F1**X - XXX - X - X

The Stand-Up headcap, the result of an innovative design that allows for excellent electrode adhesion without the need for a cumbersome chin strap, comfortable for all patients and ideal where patients require intubation or unobstructed airways.



AVAILABLE CONNECTORS FOR UNIVERSAL HEADCAPS

CODE EXAMPLE 0013. XXX - **UNI** - X - X

Universal headcaps models allow to use the same cap with EEG instruments produced by different manufacturers.

They are adaptable and compatible with most EEG instruments through the use of the adapter cable.

REF.	PATIENT SIDE	INSTRUMENT SIDE
0015.011	D -SUB 25 POLI MCH	10 x FMM 1,5 mm TP
0016.011	D -SUB 25 POLI MCH	21 x FMM 1,5 mm TP

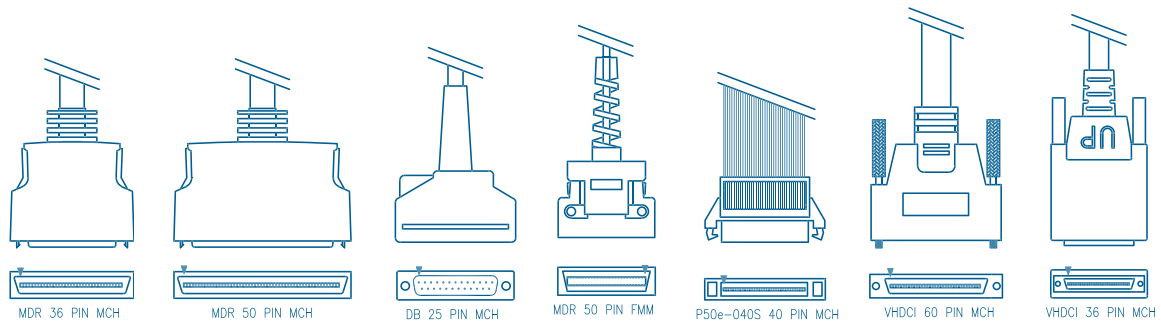


AVAILABLE CONNECTORS FOR FAST PLUG-IN HEADCAPS

CODE EXAMPLE 0013. XXX - **XXX** - X - X

BIONEN manufactures EEG headcaps with direct connection with main EEG instruments, further reducing the exam's preparation time and costs. No need of adapter cables.

The following configuration are included in our standard production, if the EEG system you need is not in the list, contact us.



MANUFACTURER	EEG INSTRUMENT MODEL	INSTRUMENT CODE	CONNECTOR TYPE
EBNeuro (ATES)	NEUROTRAVEL SMART	NTS	MDR 50 PIN MCH
EBNeuro	MIZAR - BE	MBE	MDR 50 PIN MCH
EBNeuro	BE MICRO	BEM	VHDCI 36 PIN MCH - BLACK
EBNeuro	BE LIGHT	BEL	MDR 36 PIN MCH
EBNeuro	BE LIGHT 36	B36	MDR 50 PIN MCH
EBNeuro	BE PLUS PRO/LTM	BPP	VHDCI 68 PIN MCH
EBNeuro	NEMUS 2	NEM	VHDCI 36 PIN MCH - GREY
Micromed	BRAIN QUICK	BQK	DB 25 PIN MCH
Nihon Kohden	NEUROFAX	NKH	MDR 50 PIN FMM
Deymed	TRUESCAN EEG	DEY	DB 25 PIN MCH
DX-SYSTEM	BRAINTEST PLUS	DXS	MDR 50 PIN MCH
Cadwell	ESSENTIA	CWL	MDR 36 PIN MCH
ALL	ALL	TPR	DIN 42802 (FEMALE 1,5 mm)



www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9124.BIO2**

CISQ is a member of



The International Certification Network
www.iqnet-certification.com

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

BIONEN SRL

VIA P. PETROCCHI 42/1 - 50127 FIRENZE (FI) Italy

UNITA' OPERATIVE / OPERATIVE UNITS

VIA P. PETROCCHI 42/1 - 50127 FIRENZE (FI) Italy

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione di elettrodi ed accessori per
apparecchiature elettromedicali per la rilevazione di segnali biologici
*Design and manufacturing of electrodes and accessories
for electromedical devices for detection of biological signs*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO
PER LA CERTIFICAZIONE DEI SISTEMI QUALITA' E DI GESTIONE DELLE AZIENDE
*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS
OF THE RULES FOR THE CERTIFICATION OF COMPANY QUALITY AND MANAGEMENT SYSTEMS*

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	29-06-1998	22-10-2024	13-11-2027

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



MS N° 0005MS

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo
del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment
of the entire management System within three years



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.



CERTIFICATO UE DI SISTEMA DI GESTIONE DELLA QUALITA'

Certificato n. 137/MDR

Visto l'esito delle verifiche condotte in conformità all'Allegato IX capi I e III del Regolamento (UE) 2017/745, si dichiara che il sistema completo di gestione della qualità istituito, documentato e implementato:

dal Fabbricante:

BIONEN SRL

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

SRN: IT-MF-000018461

per i seguenti dispositivi:

Agoelettrodi per elettromiografia

Cavo ECG sterile monouso

è conforme e assicura la conformità di tali dispositivi ai requisiti applicabili del Regolamento UE suddetto ed è sottoposto alla sorveglianza prevista alla sezione 3 del medesimo Allegato.

Ulteriori informazioni sono presenti nell'Allegato tecnico che costituisce parte integrante e sostanziale del presente certificato.

Questo Certificato UE è rilasciato da IMQ S.p.A. quale Organismo Notificato n. 0051 per il Regolamento (UE) 2017/745 relativo ai dispositivi medici.

Gli esami ed i test effettuati (inclusi i riferimenti alle Specifiche comuni e/o alle norme applicate) sono documentati nel pertinente Rapporto di valutazione della conformità redatto da IMQ, tracciabile attraverso la Pratica IMQ (indicata nella sezione "Storico delle revisioni" che segue) e disponibile su richiesta.

Data di prima emissione: 2023-12-20

Data di emissione precedente: 2023-12-20

Data di emissione corrente: 2024-06-04

Data di scadenza: 2028-12-19



IMQ



EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 137/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer:

BIONEN SRL

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

SRN: IT-MF-000018461

for the following devices:

Electromyography needle electrodes

Disposable sterile ECG cable

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date:	2023-12-20
Previous issue date:	2023-12-20
Current issue date:	2024-06-04
Expiry Date:	2028-12-19

IMQ

Scheda tecnica n. 1

Technical sheet no. 1

Categoria di dispositivo: Agolettrodi per elettromiografia
Device category: Electromyography needle electrodes

Classe di rischio: IIa
Risk class: IIa

Sito/i del Fabbricante / - 50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy
Manufacturer's site(s):

Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione: Non applicabile
Reference to other certificates required for the placing on the market of the covered devices: Not applicable

Condizioni o limitazioni di validità: Nessuna
Conditions for or limitations to the validity: None

Altre informazioni rilevanti: Nessuna
Other relevant data: None

Dati dei dispositivi: I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR' rev. 2 del 2024/06/04 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.

Device data: Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 137/MDR' rev. 2 dated 2024/06/04 attached to this certificate. This document is integral and substantial part of this certificate.

Scheda tecnica n. 2

Technical sheet no. 2

Categoria di dispositivo: **Cavo ECG sterile monouso**
Device category: *Disposable sterile ECG cable*

Classe di rischio: **Ila**
Risk class: *Ila*

Sito/i del Fabbricante / **- 50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy**
Manufacturer's site(s):

Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione: **Non applicabile**
Reference to other certificates required for the placing on the market of the covered devices: *Not applicable*

Condizioni o limitazioni di validità: **Nessuna**
Conditions for or limitations to the validity: *None*

Altre informazioni rilevanti: **Nessuna**
Other relevant data: *None*

Dati dei dispositivi: **I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR' rev. 2 del 2024/06/04 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.**

Device data: *Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 137/MDR' rev. 2 dated 2024/06/04 attached to this certificate. This document is integral and substantial part of this certificate.*

Storico delle revisioni

Revision history

N. No.	Data Date	Riferimento Pratica IMQ Reference to IMQ Project	Descrizione Description
1	2023-12-20	DM23-0076563-01	Prima emissione <i>First Issue</i>
2	2024-06-04	DM24-0101717-01	Estensione per inserimento nuova categoria di dispositivo ("Cavo ECG sterile monouso"); aggiornamento per correzione di refuso nell'identificazione di una marca di "Agoelettrodi per elettromiografia" <i>Extension for additional new device category ("Disposable sterile ECG cable"); updating for correction of typo in the identification of a trade mark of "Electromyography needle electrodes"</i>

Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Agoelettrodi per elettromiografia Device category: Electromyography needle electrodes
Modello/i Model(s): ./.
Numero/i di catalogo (REF) / 028W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica il tipo di sensore: 0 = Standard - 1 = Premium XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)
Nome/i commerciale/i Trade name(s): ./.
Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./.
Numero/i di catalogo (REF) / 029W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica il tipo di sensore: 0 = Standard - 1 = Premium XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)
Nome/i commerciale/i Trade name(s): ./.
Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./.
Numero/i di catalogo (REF) / 0247-XXYY-ZZZ Catalogue number(s) (REF): Dove: XX indica il Diametro dell'ago (da 0,30 a 0,55 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)
Nome/i commerciale/i Trade name(s): ./.
Marca/Marche Trade mark(s): BIONEN
Modello/i Model(s): ./.
Numero/i di catalogo (REF) / 027W-XXYY-ZZZ Catalogue number(s) (REF): Dove: W indica la Tipologia di punta (0 = ipodermica, 1 = tonda, 2 = tonda marcata) XX indica il Diametro dell'ago (da 0,30 a 0,90 mm) YY indica la Lunghezza dell'ago (da 15 a 75 mm) ZZZ indica il tipo di confezionamento secondario (da 5 a 100 pz)
Nome/i commerciale/i Trade name(s): ./.
Marca/Marche Trade mark(s): BIONEN

Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Agolettrodi per elettromiografia
Device category: Electromyography needle electrodes

Modello/i Model(s): ./.

Numero/i di catalogo (REF) / NKD-NMYYZZ(P)

Catalogue number(s) (REF): Dove:

NKD-NM valore fisso che identifica la marca NIHON KHODEN

YY indica il Diametro dell'ago (da 0,30 a 0,55 mm)

ZZ indica la Lunghezza dell'ago (da 15 a 75 mm)

P indica il tipo di sensore

- "assente" = Standard
- P = Premium

Nome/i commerciale/i Trade name(s): ./.

Marca/Marche Trade mark(s): **NIHON KHODEN**



Elenco dei dispositivi oggetto del Certificato UE n. 137/MDR

List of the devices covered by the EU Certificate no. 137/MDR

rev. 2 del of 2024/06/04

Categoria di dispositivo: Cavo ECG sterile monouso
Device category: Disposable sterile ECG cable

Modello/i Model(s): ./.

Numero/i di catalogo (REF) / 0210.XXX

Catalogue number(s) (REF): Dove:

XXX indica la Lunghezza del cavo (da 100 a 250 cm)

Nome/i commerciale/i Trade name(s): **FasTip**

Marca/Marche Trade mark(s): **BIONEN**