DFBAD01STD / DFBAD01PRC / RS4-DFB01PRC / RS4-DFBAD01PRC / RS4-DFBPED01PRC CE

DFBPED01PRC CE 0068

IT. **ELETTRODI MULTIFUNZIONE MONOUSO**
EN. **DISPOSABLE MULTIFUNCTION ELECTRODES**
FR. **ÉLECTRODES MULTIFONCTIONS À USAGE UNIQUE**
DE. **MULTIFUNKTIONS-EINWEGELEKTRODEN**
NL. **MULTIFUNCTIONELE WEGWERPELEKTRODEN**
ES. **ELECTRODOS MULTIFUNCIONALES DESECHABLE**
PT. **ELÉTRODOS MULTIFUNÇÃO DESCARTÁVEIS**
RU. **МНОГОФУНКЦИОНАЛЬНЫЕ ОДНОРАЗОВЫЕ ЭЛЕКТРОДЫ**
EL. **ΗΛΕΚΤΡΟΔΙΑ ΠΟΛΛΑΠΛΩΝ ΛΕΙΤΟΥΡΓΙΩΝ ΜΙΑΣ ΜΟΝΟ ΧΡΗΣΗΣ**
SV. **MULTIFUNKTIONELLA ELEKTRODER FÖR ENGÅNGSBRUK**
HR. **VIŠENAMJENSKE ELEKTRODE ZA JEDNOKRATNU UPOTREBU**
PL. **ELEKTRODY WIELOFUNKCYJNE JEDNORAZOWEGO UŻYTKU**
RO. **ELECTROZI MULTIFUNCȚIONALI DE UNICĂ FOLOSINȚĂ**
HU. **EGYSZERHASZNÁLATOS TÖBBFUNKCIÓS ELEKTRÓDÁK**
BG. **МНОГОФУНКЦИОНАЛНИ ЕЛЕКТРОДИ ЗА ЕДНОКРАТНА УПОТРЕБА**
LT. **DAUGIAFUNKCIAI VIENKARTINIAI ELEKTRODAI**
SK. **JEDNORÁZOVÁ MULTIFUNKČNÁ ELEKTRÓDA**
TR. **TEK KULLANIMLIK ÇOK İŞLEVLİ ELEKTROTLAR**
UK. **ОДНОРАЗОВИХ БАГАТОФУНКЦІОНАЛЬНИХ ЕЛЕКТРОДІВ ДЛЯ ДЕФІБРИЛЯТОРА**

PROGETTI S.r.l.
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Rev.1.0 05/2024

TD2.2-DFBseries Rev.1.0-2024-05

EN

progetti
Medical Equipment Solutions

DISPOSABLE MULTIFUNCTION ELECTRODES

OPERATING INSTRUCTION

Before use read carefully the safety information detailed in the following instructions for use.

A pair of adhesive electrodes, which are equipped with gel, are contained in every pouch. They can be used in place of manual reusable paddles and they have a direct connection with therapy cables and defibrillators.
They allow the operator to effectively act in the arrhythmia treatment related to the uses listed below, without the risk of accidental electrocution.

INDICATIONS

PROGETTI disposable multifunction electrodes are indicated for:

- transthoracic external defibrillation,
- transthoracic synchronized cardioversion,
- transthoracic ECG Monitoring,
- temporary transthoracic cardiac pacing (non-invasive),

The device is intended to be used in non-sterile environment by qualified healthcare personnel and/or, if applicable, by people trained for CPR (Cardio-Pulmonary Resuscitation) and for the use of AED (Automatic External Defibrillator).

Adult models are addressed to patients that weigh more than 25 kg.
Paediatric models are addressed to children that weigh less than 25 kg.

CONTRAINDICATIONS

- The use of PROGETTI adult disposable electrodes is generally contraindicated in patients younger than 8 years old (weight less than 25kg), but can be used if the size of the chest allow it, taking care that one pad do not come in contact with the other one and following the operating instructions of the defibrillator for energy to be delivered.
- The use of PROGETTI disposable multifunction electrodes in versions for adult is contraindicated in children aged less than 12 months (weight less than 10kg).
- The use of PROGETTI pediatric disposable electrodes is contraindicated in patients older than 8 years old (weight more than 25kg);
- Do not apply on skin that shows signs of irritation or injury.

MODE OF USE

External Defibrillation and synchronized cardioversion: the PROGETTI disposable multifunction electrodes are able to transfer to the patient the electrical energy supplied by the defibrillator up to a maximum value of 360J in the adult or adult/paediatric versions and of 100J in the paediatric version;**.** they can withstand up to 50 defibrillation shocks.
The depolarization of the critical mass of the myocardium, which is essential for the success of the therapy, is only possible if it is crossed by a current of appropriate intensity: the active surface of the electrodes is optimized for this purpose. It is therefore appropriate, in addition to a targeted selection of the positioning sites, to apply the adhesive pads in such a way that their contact surface with the skin is maximum. The choice of power to supply is at the discretion of the operator.
The Guidelines for paediatric cardiopulmonary resuscitation recommend a supply of energy of 2-4J/kg; the recommended starting level is of 2J/kg and it is preferable not to exceed 100J in order to avoid burns**.**.
WARNING. Do not supply a shock with reusable metal paddle above the electrodes.
Non-invasive transthoracic pacing: PROGETTI disposable multifunction electrodes can be used for non-invasive transthoracic pacing (with defibrillators provided with such function). To minimize the threshold of pacing it is appropriate to apply the adhesive pads in the manner described above. It is also necessary to have a good understanding of the equipment and follow the manufacturer's instructions.

WARNING. It is good practice to replace PROGETTI disposable multifunction electrodes after 8 hours, checking every 30 minutes, in case of prolonged pacing, the skin of the patient for signs of irritation.

WARNING. Replace PROGETTI disposable multifunction electrodes after 30 minutes if the supplied pulses are monophasic and longer than 20ms.

ECG monitoring: PROGETTI disposable multifunction electrodes can also be used for ECG monitoring.

WARNING. If the tracing is not sufficiently clear, use an ECG patient cable, if it is present, and a separate set of ECG electrodes.

MODE OF APPLICATION

- In case of pre-connectable electrodes, keep the connector plugged into the socket of defibrillator, complying with device instructions.
- Uncover the chest and prepare the skin. Remove excessive hairs. Slightly abrade the skin surface to reduce the contact impedance. Avoid applying the adhesive pad on the nipple or breast tissue.
- Remove any residue (dirty, greasy and debris), using non-flammable cleaners. Finally, make sure the application sites are clean and dry.
- Open the package and remove multifunction electrodes.
- Gently remove the protective liner, starting from the tab to expose the adhesive and conduction areas.
- The points where it is possible to apply the adhesive electrodes are listed in the following paragraph titled “PLACEMENT AND POLARITY”.
- Apply the adhesive pads one-to-one starting with one side and pressing progressively over the entire surface to avoid the formation of air bubbles and ensure complete adhesion to the skin. Keep the adhesive pads well separated one from the other and be careful not to overlap them with other objects (ECG electrodes, cables, transdermal patches, clothing etc.).
- Do not reposition the adhesive pads once applied. If the position must be changed, remove and replace with new multifunction electrodes. The repositioning implies a reduction of adhesivity and a resulting increase of burn related risk.
- Plug the electrodes connector into the socket of defibrillator or the patient cable, complying with the instructions for use of the defibrillator (if they are not connected like in case of pre-connectable electrodes).

- For on demand pacing, separately connect ECG monitoring electrodes.
- After the end of treatment remove each of the adhesive pads pulling it from one edge delicately, so as not to irritate the skin of the patient.
- Remove the connector from the socket of defibrillator and dispose of the electrodes together with their packaging.

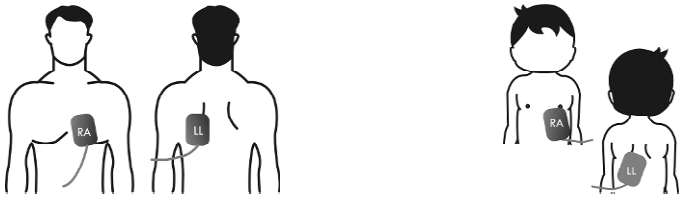
PLACEMENT AND POLARITY

The international guidelines indicate various placements as equally effective for the treatment of atrial or ventricular arrhythmias.
The following figures show the application sites commonly used and recommended by most manufacturers of defibrillators. Choose the most appropriate points of application of the therapy according to manufacturer's instructions for use of the defibrillator to be used.

For ease of placement and for training purposes, the anterior-lateral side (Fig.1) is preferred for arrhythmias defibrillation and cardioversion; the anterior-posterior side (Fig.2) is more common in hemodynamics and in transthoracic pacing and recommended in case of use of electrodes for adults on pediatric patients.

Fig.1
- Defibrillation
- Cardioversion
- Pacing
- Monitoring (it provides a Lead II track)

Fig.2
- Pacing
- Monitoring
- Defibrillation
- Cardioversion



To maintain the proper signal polarity, apply the electrode pads in the indicated positions (the apex is identified by the symbol of the heart). However note that for the purpose of the therapy, it is not relevant which electrode pad (apex / sternum) is placed in one of the two positions.

SIDE EFFECTS
- The adhesive may cause light cutaneous irritation.
- The prolonged transthoracic stimulation or the repeated administration of defibrillation shock may cause more or less noticeable skin reddenings according to the supplied energy.
- Insufficient in adhesion and/or air presence under the electrode may cause burnings.

PRECAUTIONS AND WARNINGS
- Use the device only with compatible defibrillators. Check the compatibility on the package.
- Read the instructions for use of the defibrillator, with particular attention on the placement of multifunction electrodes, their polarity and the power to be supplied.
- In paediatrics and for some models of automatic defibrillators the use of specific reducing power devices or the adoption of special precautions may be required. Always pay a special attention to energy levels set on the defibrillator and that can be delivered to the paediatric patient (see section "MODE OF USE").

ATTENTION

Do not use paediatric multifunction electrodes marked with this symbol with automatic defibrillators.

Paediatric multifunction electrodes marked with the symbol shown beside are indicated for use with automatic defibrillators.

- The electrode choice should be based on the evaluation of chest size and weight of the patient. Paediatric electrodes used beyond the specified energy limit may cause also major skin burns; on the contrary the extended active surface of adult electrodes may jeopardize the therapy when used for pediatric treatment.
- After an extended period of transthoracic pacing the ability to detect the evoked ECG signal can be reduced. In this case it is necessary to provide by a separate set of ECG electrodes for the collection of the evoked signal.
- Replace the multifunction electrodes after 24 hours from their application on the patient's skin.
- Do not use the electrodes if they exceed the expiration date reported on the package.
- The traceability data and the device expiration date are detailed only on the package: save the package or write REF and LOT # for possible references to the used electrodes.
- Check that the packaging is intact: do not use the product otherwise.
- Open the package of the multifunction electrodes only before they use. The adhesive pads must be attached on the skin of patient immediately after the removal of the protective covering.
- Do not use the multifunction electrodes if the gel is removed from the support or if it is ripped, torn or dry. Any discoloration localized on gel or on conductive foil does not affect the functionality of the product.
- Do not use the multifunction electrodes if during removal of the protective coating the product is damaged (eg. the insulating coating of the contact has detached or there are tears in the foam support and/or in the electrode).
- Do not bend, cut nor squash the adhesive pads.
- Do not use the multifunction electrodes if the connector, or the cable appear to be damaged.
- Check on the operating instructions of the defibrillator at which safety distances the devices (surgeon's electric knife, RF ablators, diathermy equipment, mobile phones, etc.) that emit strong electromagnetic interferences must be placed. Position the defibrillator / electrode system at a distance of at least one and a half times the recommended separation distances.
- The electrodes and their cable are made of ferromagnetic materials, therefore they must not be used in presence of the intense magnetic field supplied from a magnetic resonance imaging (MRI).

- To prevent accidental damage from electric shock, ensure that during discharge operators are not in contact with the electrode pads, with the patient, or with conductive parts close to the patient.
- When defibrillators are used near oxygen sources or other flammable gases, use extreme care to avoid risk of fire or explosion.
- The product neither is sterile nor can be sterilized.
- The device is disposable - do not reuse. The reuse can imply: material alterations and the loss of the device functional characteristics.

POTENTIAL COMPLICATIONS

There are no complications related to the use of multifunction electrodes.

WARNING. Defibrillator discharge may cause irregularities in the operation of an implanted pacemaker/defibrillator; apply the multifunction electrodes at a distance of at least 8cm. After defibrillator discharge check its operation.

WARNING. If the chosen energy level is insufficient the success of therapy may be jeopardizing. On the contrary, higher levels may modify the enzyme structure without actual evidence of myocardial damage.

PRODUCT LIFE AND STORAGE

Check the expiration date printed on the package.
The product should be stored in its original packaging in rooms with environment conditions of temperature and relative humidity, specified on the label. The packaged electrodes can be exposed to extreme temperatures, between -30°C and +65°C, for up to 7 days.
A prolonged and/or repeated conservation to extreme temperatures reduces the residual life of the device.
Overlapping of weights on the packaging could damage the product.

WASTE DISPOSAL

Waste coming from health facilities must be disposed of according to the regulation in force.

GENERAL NOTES

If a serious incident occurs while using this device or as a result of its use, please report it to the Manufacturer and to your national authority. For any malfunction or defect of the device, inform the Manufacturer's Quality Service.

CE 0068	Compliant with current European legislation on Medical Devices		Manufacturer
REF	Catalogue number	LOT	Batch code
X	Quantity of pieces		Date of manufacture
	Use by	MAX MIN	Temperature limitation
	Operating temperature limits	%	Humidity limitation
	Keep away from sunlight		Keep dry
	Consult instructions for use		Do not reuse
LATEX	Does not contain natural rubber latex	MD	Medical Device
	Do not use if package is damaged	UDI	Unique Device Identifier
NON STERILE	Non-sterile	/	1 Pouch/2 Pads

DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITÀ UE

This declaration is issued under exclusive responsibility of the Manufacturer.
Questa dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Elettrodi Monouso Multifunzione per defibrillatore** *Disposable Multifunction Electrodes for defibrillator*
NAME OF MEDICAL DEVICE (REF) ***NOME DEL DISPOSITIVO MEDICO***	***DFBAD01STD, DFBAD01PRC***
INTENDED USE ***DESTINAZIONE D'USO***	External cardiac defibrillation *Defibrillazione cardiaca esterna*
CND CODE (ref.13/03/2018 classification) ***CODICE CND*** *(rif. classificazione del 13/03/2018)*	**C020401**
GMDN CODE ***CODICE GMDN***	**44771 - External defibrillator electrode, adult, single-use**
BASIC UDI-DI (ref. Ann.VI part C, Reg. 2017/745) ***UDI-DI di BASE*** *(rif. All.VI parte C, Reg. 2017/745)*	**805414531ELE-DFBADL6**
CLASS (ref. Ann. VIII, Reg. 2017/745) ***CLASSE*** *(rif. All.VI parte C, Reg. 2017/745)*	*I* (according to Rule 1 of Annex VIII) *(ai sensi della Regola 1 dell'Allegato VIII)*
BATCH NUMBER (LOT) ***NUMERO DI LOTTO***	*If you want to receive a dedicated declaration of conformity with the lot number of your device and/or an updated one, please contact Progetti S.r.l. at the email address **info@progettimedical.com**. **Per ricevere la dichiarazione di conformità dedicata allo specifico numero di lotto del dispositivo e/o una dichiarazione aggiornata, si prega di contattare Progetti s.r.l. all'indirizzo e-mail **info@progettimedical.com**.*
MANUFACTURER (trademark, name, address) ***FABBRICANTE*** *(marchio, nome, indirizzo)*	progetti® Medical Equipment Solutions **PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
MANUFACTURER SRN (ref. art.31, Reg. 2017/745) ***SRN DEL FABBRICANTE*** *(rif. art. 31, Reg. 2017/745)*	**IT-MF-000008116**
EC MARKING (ref. Reg. 2017/745) ***MARCATURA CE*** *(rif. Reg. 2017/745)*	CE
CONFORMITY ASSESSMENT ROUTE **PROCEDURA VALUTAZIONE CONFORMITÀ**	**Annex II, III** *Allegato II, III*
FIRST ISSUE DATE OF DECLARATION OF EU CONFORMITY ***DATA DI PRIMA EMISSIONE DELLA DICHIARAZIONE DI CONFORMITÀ EU***	28/05/2024

We declare that the above-mentioned medical device is compliant with **Regulation (EU) 2017/745** and subsequent amendments.

*Si dichiara che il dispositivo medico sopra descritto è conforme al **Regolamento (UE) 2017/745** e successive modifiche.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **28/05/2024**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITÀ UE

This declaration is issued under exclusive responsibility of the Manufacturer.
La presente dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Elettrodi Monouso Multifunzione per defibrillatore** *Disposable Multifunction Electrodes for defibrillator*
NAME OF MEDICAL DEVICE (REF) ***NOME DEL DISPOSITIVO MEDICO***	**DFBPED01PRC**
INTENDED USE ***DESTINAZIONE D'USO***	External cardiac defibrillation *Defibrillazione cardiaca esterna*
CND CODE (ref.13/03/2018 classification) ***CODICE CND*** *(rif. classificazione del 13/03/2018)*	**C020401**
GMDN / UMDNS CODE ***CODICE GMDN / UMDNS***	**41587 - External defibrillator electrode, paediatric, single-use**
BASIC UDI-DI (ref. Ann.VI part C, Reg. 2017/745) ***UDI-DI di BASE*** *(rif. All.VI parte C, Reg. 2017/745)*	**805414531ELE-DFB4P**
CLASS (ref. Ann. IX, Dir. 93/42/EEC) ***CLASSE*** *(rif. All. IX, Dir.93/42/CEE)*	II b
APPLIED STANDARDS ***NORME APPLICATE***	**EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013+A12:2014, EN 60601-1-2:2015, EN 60601-2-4:2011+A1:2019, EN 62366-1:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
BATCH NUMBER (LOT) ***NUMERO DI LOTTO***	*If you want to receive a dedicated declaration of conformity with the lot number of your device and/or an updated one, please contact Progetti S.r.l. at the email address **info@progettimedical.com**. *Per ricevere la dichiarazione di conformità dedicata allo specifico numero di lotto del dispositivo e/o una dichiarazione aggiornata, si prega di contattare Progetti s.r.l. all'indirizzo e-mail **info@progettimedical.com***
MANUFACTURER (trademark, name, address) ***FABBRICANTE*** *(marchio, nome, indirizzo)*	progetti® Medical Equipment Solutions **PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
MANUFACTURER SRN (ref. art.31, Reg. 2017/745) ***SRN DEL FABBRICANTE*** *(rif. art. 31, Reg. 2017/745)*	**IT-MF-000008116**
NOTIFIED BODY ***ENTE NOTIFICATO***	MTIC INTERCERT MTIC InterCert S.r.l. (Notified Body N°**0068**) Via Moscova, 11 20017 Rho (MI) - ITALY
EC MARKING (ref.Dir.93/42/EEC) ***MARCATURA CE*** (rif.Dir.93/42/CEE)	CE 0068
N° EC CERTIFICATE ***N° CERTIFICATO CE***	**0068/QCO-DM/004-2015 Rev.01**
PROCEDURE OF EVALUATION (ref. Dir.93/42/EEC) ***PROCEDURA DI VALUTAZIONE*** *(Rif. Dir.93/42/CEE)*	**Annex II** (point 4 is excluded) **Allegato II** (punto 4 escluso)
EXPIRE DATE OF EC CERTIFICATE ***DATA DI SCADENZA DEL CERTIFICATO CE***	**31/12/2028** (according to Reg. (EU) 2023/607) (ai sensi del Reg. (UE) 2023/607)
FIRST ISSUE DATE OF EC CERTIFICATE ***DATA DI PRIMA EMISSIONE DEL CERTIFICATO CE***	06/05/2015

We herewith declare that the described above medical device is compliant to **Directive 93/42/EEC and subsequent amendments** and it can be put in the market according to **art.120 of Regulation (EU) 2017/745 and subsequent amendments**.
Also, the product is manufactured based on **Directive 2011/65/EEC** (RoHS) and subsequent amendments.

*Si dichiara che il dispositivo medico sopra descritto è conforme alla **Direttiva 93/42/CEE e ss.mm.ii.** e può essere immesso sul mercato ai sensi dell'**art.120 del Regolamento (UE) 2017/745** e successive modifiche.*
*Inoltre, il dispositivo medico soddisfa i requisiti applicabili della **Direttiva 2011/65/CEE** (RoHS) e successive modifiche.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **24/05/2024**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITÀ UE

This declaration is issued under exclusive responsibility of the Manufacturer.
Questa dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Elettrodi Monouso Multifunzione per defibrillatore** *Disposable Multifunction Electrodes for defibrillator*
NAME OF MEDICAL DEVICE (REF) ***NOME DEL DISPOSITIVO MEDICO***	***RS4-DFB01PRC, RS4-DFBAD01PRC, RS4-DFBPED01PRC***
INTENDED USE ***DESTINAZIONE D'USO***	External cardiac defibrillation *Defibrillazione cardiaca esterna*
CND CODE (ref.13/03/2018 classification) ***CODICE CND** (rif. classificazione del 13/03/2018)*	**C020401**
GMDN CODE ***CODICE GMDN***	**RS4-DFB01PRC** **47055 - External defibrillator electrode, adult & paediatric, single-use** **RS4-DFBAD01PRC** **44771 - External defibrillator electrode, adult, single-use** **RS4-DFBPED01PRC** **41587 - External defibrillator electrode, paediatric, single-use**
BASIC UDI-DI (ref. Ann.VI part C, Reg. 2017/745) ***UDI-DI di BASE** (rif. All.VI parte C, Reg. 2017/745)*	**805414531ELE-RS4DFBBV**
CLASS (ref. Ann. VIII, Reg. 2017/745) ***CLASSE** (rif. All.VI parte C, Reg. 2017/745)*	*I* (according to Rule 1 of Annex VIII) *(ai sensi della Regola 1 dell'Allegato VIII)*
BATCH NUMBER (LOT) ***NUMERO DI LOTTO***	*If you want to receive a dedicated declaration of conformity with the lot number of your device and/or an updated one, please contact Progetti S.r.l. at the email address **info@progettimedical.com**. **Per ricevere la dichiarazione di conformità dedicata allo specifico numero di lotto del dispositivo e/o una dichiarazione aggiornata, si prega di contattare Progetti s.r.l. all'indirizzo e-mail **info@progettimedical.com**.*
MANUFACTURER (trademark, name, address) ***FABBRICANTE** (marchio, nome, indirizzo)*	**PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
MANUFACTURER SRN (ref. art.31, Reg. 2017/745) ***SRN DEL FABBRICANTE** (rif. art. 31, Reg. 2017/745)*	**IT-MF-000008116**
EC MARKING (ref. Reg. 2017/745) ***MARCATURA CE** (rif. Reg. 2017/745)*	CE
CONFORMITY ASSESSMENT ROUTE **PROCEDURA VALUTAZIONE CONFORMITÀ**	**Annex II, III** *Allegato II, III*
FIRST ISSUE DATE OF DECLARATION OF EU CONFORMITY ***DATA DI PRIMA EMISSIONE DELLA DICHIARAZIONE DI CONFORMITÀ UE***	27/05/2021

We declare that the above-mentioned medical device is compliant with **Regulation (EU) 2017/745** and subsequent amendments.

*Si dichiara che il dispositivo medico sopra descritto è conforme al **Regolamento (UE) 2017/745** e successive modifiche.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **24/05/2024**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

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