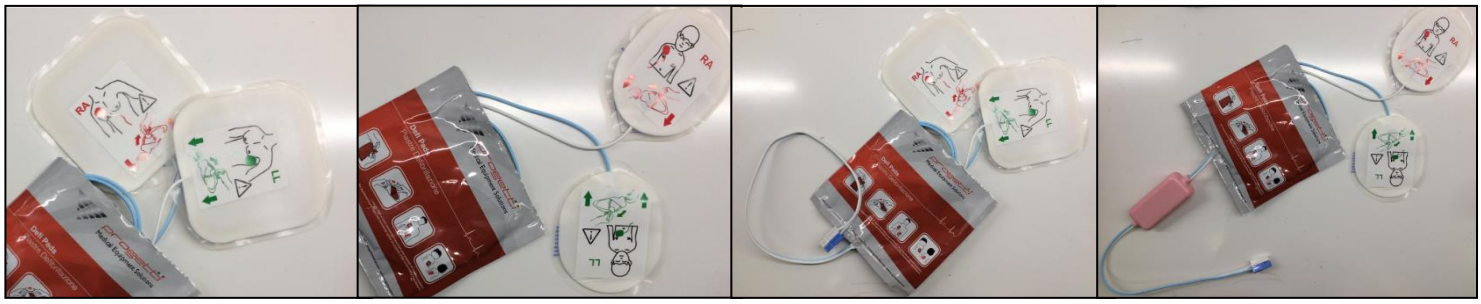
progetti
Medical Equipment Solutions

Elettrodi Monouso Multifunzione per Defibrillatore

(defibrillazione, cardioversione sincronizzata, stimolazione cardiaca transcutanea, monitoraggio ECG)

Manuale d'Uso

DFBAD01STD / DFBAD01PRC (Adulti)
DFBPED01STD / DFBPED01PRC (Pediatrici)



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Progetti S.r.l.
Strada del Rondello, 5
10028 Trofarello (TO), Italy

V 2.1
Rev. 02/2021

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**

CS **JEDNORÁZOVÉ MULTIFUNKČNÍ ELEKTRODY**

[1] Ian Jacobs, Kjetil Sunde, et al. “Part 6: Defibrillation. 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations” Circulation 2010;122:S325-S337
[2] Jerry Nolan et al. “European Resuscitation Council Guidelines for Resuscitation 2010” Resuscitation Vol. 81, 2010, Editor Jerry Nolan, Bath, UK
[3] A. Luciano et al., "BODY-MASS INDEX REFERENCE CURVES FOR CHILDREN AGED 3-19 YEARS FROM VERONA, ITALY", European journal of clinical nutrition, 51(1), 1997, pp. 6-10
[4] Edward J. Sondik, et al. “2000 CDC Growth Charts for the United States: Methods and Development” Vital and Health Statistics. Series 11, Number 246: May 2002
[5] John M. Field et al. “2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care” Circulation 2010, 122:S640-S946 Journal of the American Heart Association Editor Mary Fran Hazinski, RN, MSN
[6] Luis A. Pagan-Carlo, Kirk T. Spencer, et al. “Transthoracic defibrillation: importance of avoiding electrode placement directly on the female breast” Journal of American College of Cardiology 1996;27:449-452
[7] Edward A. Panacek, Mark A. Munger et al. “Report of nitropatch explosions complicating defibrillation” American Journal of Emergency Medidicine 1992;10:128-9
[8] Keith Wrenn “The hazards of defibrillation through nitroglicerin patches” Annals of Emergency Medicine 1990;19:1327-8
[9] Johannes C. Manegold, Carsten W. Israel et al. “External cardioversion of atrial fibrillation in patients with implanted pacemaker or cardioverter-defibrillator sistems: a randomized comparison of monophasic and biphasic shock energy application” European Heart Journal 2007;28:1731-8

EN

DISPOSABLE MULTIFUNCTION ELECTRODES
OPERATING INSTRUCTION

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

IMPORTANT
The product is intended for use in non-sterile environment by authorized personnel only.
Before using the product, the user should deeply understand these instructions.

DESCRIPTION
The disposable multifunction electrodes *PROGETTI* are constituted by a pair of adhesive pads provided with gels and direct connection to cables and defibrillators which may be used in place of the manuals reusable paddles [1].

PACKAGING
Each pair of PROGETTI disposable multifunction electrodes is packaged in sealed envelopes of opaque material suitable to protect the gel from light and moisture. Envelopes are included in the carton sales package along with a copy of the operating instructions.

INDICATIONS
The disposable multifunction electrodes *PROGETTI* are indicated for:
• Transthoracic external defibrillation.
• Transthoracic synchronized cardioversion.
• Transthoracic ECG Monitoring.
• Temporary transthoracic cardiac pacing (non-invasive).

PROGETTI disposable multifunction electrodes allow the user to effectively operate in the treatment of rhythm disorders related to the above-mentioned applications, without the risk of accidental electrocution related to the use of normally available reusable paddles.

CONTRAINDICATIONS
- PROGETTI disposable multifunction electrodes for adults are generally contraindicated in patients younger than 8 years old [2] (weighing less than 25kg [3][4])), 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. Follow the operating instructions of the defibrillator for energy to be delivered.
- The use of PROGETTI disposable multifunction electrodes in versions for adult or adult/paediatric is generally contraindicated in patients aged less than 12 months (weighing less than 10kg).
- The use of PROGETTI pediatric disposable multifunction electrodes is generally contraindicated in patients older than 8 years old [2] (weighing more than 25kg [3][4]);
- 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 version [1], of 300J for adult/paediatric unic version and of 100J in the paediatric version [5].
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. In paediatric applications the Guidelines for cardiopulmonary resuscitation recommend a supply of energy of 2-4J / kg; the recommended starting level is of 2 J / kg and it is preferable not to exceed 100J in order to avoid burns [5].

ATTENTION PROGETTI disposable multifunction electrodes can withstand up to 50 defibrillation shocks.

ATTENTION Do not supply a shock with manual metal paddle above the disposable electrode pads or ECG electrodes.

Non-invasive transthoracic pacing: PROGETTI disposable multifunction electrodes can be used for non-invasive transthoracic pacing. To minimize the threshold of pacing it is appropriate to apply the adhesive plates in the manner described above. It is also necessary to have a good understanding of the equipment you want to use and follow the manufacturer's instructions.

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

ATTENTION 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.

ATTENTION 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

- The multifunction electrodes can be applied to the patient even in the mere suspicion that a severe arrhythmic disease may develop.
- The points where it is possible to apply the adhesive electrodes are listed in “PLACEMENT AND POLARITY”.
- Uncover the chest and prepare the skin. Remove excessive hair [1]. Slightly abrade the skin surface to reduce the contact impedance. Avoid applying the adhesive pad on the nipple or breast tissue [6].
- Remove any debris (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.
- In case of multifunctional electrodes with clips remove the protective support.
- 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.) [7][8].
- Do not replace the adhesive pads once applied. If the position must be changed, remove and replace with new multifunction electrodes.
- To remove the adhesive plate without irritating the patient's skin, lift an edge and gently pull back. Hold at the same time the skin with the other hand.
- For multifunctional electrodes without clip: connect the electrodes to the defibrillator or the adapter cable by following the instructions for use of the defibrillator.
- For multifunctional electrodes with clips: connect the clip to the cable of the defibrillator for the correct polarity, observing the instructions for use of the defibrillator.
- For on demand pacing, separately connect ECG monitoring electrodes.

POSITIONING AND POLARITY

The international guidelines indicate various placements as equally effective for the treatment of atrial or ventricular arrhythmias [1][5].

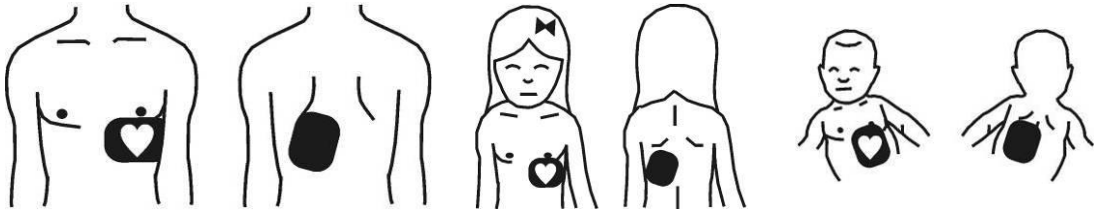
The following figures show the application sites commonly used and recommended by most manufacturers of defibrillators. Choose the most appropriate points of application of the therapy according to manufacturer's instructions for use of the defibrillator to be used.

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 track Lead II)

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 [2].
Regarding the polarity of the electrodes in unique version adult/pediatric, follow the directions on the labels of the electrode pad (according to the instructions of the manufacturer of the defibrillator to be used).

SIDE EFFECTS
- Plate 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.
- A lack in adhesion and/or air presence under the electrode may cause burnings.

PRECAUTIONS AND WARNINGS
- Use the product only on defibrillators brands indicated on the labels.
- Check that the product is compatible with the specific model of defibrillator intended to be used.
- 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 the symbol shown beside 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 for the collection of the evoked signal by a separate set of ECG electrodes.
- Replace the multifunction electrodes after 24 hours from their application on the patient's skin.
- Check the expiration date on the package. Do not use after this date.

- Do not use multifunction electrodes if removed from the envelope for more than 24 hours. The adhesive pads are to be applied within 30 minutes after removal of the protective coating.
- Check that the packaging is intact: do not use the product otherwise.
- 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, do not cut and do not squash the adhesive pads.
- Do not use the multifunction electrodes if the connector, the cable or the clips 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.
- 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 product is disposable. For use on a single patient. Discard after use.

POTENTIAL COMPLICATIONS

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

ATTENTION: The defibrillator discharge may cause irregularities in the operation of an implanted pacemaker/defibrillator [1]; apply the multifunction electrodes at a distance of at least 8cm [9]. After defibrillator discharge check its operation.

ATTENTION: 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 storage at extreme temperatures must be limited to short periods (24 hours at -30°C or +65°C). Prolonged storage at extreme temperatures can shorten the life of the product.

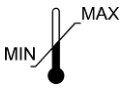
ATTENTION: The overlap of weights on the packaging could damage the product.

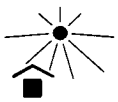
DISPOSAL

Refuses deriving from health structures must be disposed in according to the regulation in force.

WARRANTY AND LIMITATIONS

PROGETTI S.p.A. guarantees that the product complies with Directive 93/42/EEC. No responsibility may be ascribed to the producer who shall not be held liable for medical costs, director indirect damage due to lacking function or malfunction of the above product, when used differently from the instruction for use. We recommend to report opportunely any malfunction or defect of the product to PROGETTI Quality Assurance Service.

	CE 0068		REF	LOT					
IT	Conformità Europea	Prodotto da	Numero di Catalogo	Numero di Lotto	Numero pezzi per confezione	Data di Produzione	Usare entro il	Limiti temperatura	Temperatura operativa
EN	European Conformity	Manufactured by	Catalogue Number	Batch number	Pcs. per box/pack	Production date	Use before	Temperature limits	Operating temperature limits
FR	Conformité Européenne	Produit par	Numéro de catalogue	Numéro de Lot	Numéro de pièce par emballage	Date de production	Utiliser avant le	Limites de température	Température de fonctionnement
DE	CE Prüfzeichen	Erzeugt von	Katalognummer	Postenummer	Stück/ Packung	Erzeugungsdatum	Verwendbar bis	Temperaturbegrenzungen	Betriebstemperatur
NL	Europese conformiteit	Geproduceerd door	Catalogus-nummer	Partijnummer	Aantal artikels per verpakking	Productiedatum	Te gebruiken binnen	Temperatuur limieten	Temperatuur limieten
ES	Conformidad Europea	Fabricado por	Número de catálogo	Número de Loto	Piezas por bolsa o paquete	Fecha de producción	Usar antes de	Límites de temperatura	Limites de temperatura de funcionamiento
PT	Conformidade Europeia	Fabricado por	Número de Catálogo	Número de Grupo	Unidades por embalagem	Data de Fabrico	Usar antes de	Limites de temperatura	Limites da temperatura de funcionamento
RU	Соответствие нормам ЕС.	Изготовитель	Номер по каталогу	Номер партии/изделия	Кол-во в коробке/упаковке	Дата изготовления	Использовать до	Ограничения по температуре	Пределы рабочей температуры
EL	Ευρωπαική συμμόρφωση.	Κατασκευασμένο από	Αριθμός καταλόγου	Αριθμός λαχειοφόρου αγοράς	Τεμάχια ανά κουτί/πακέτο	Ημερομηνία παραγωγής	Να χρησ/θεί πριν από	Ορια θερμοκρασίας	Όρια θερμοκρασίας λειτουργίας
SV	Överensstämmer med EG-direktiven	Tillverkad av	Artikelnummer	Satsnummer	Antal per låda/förpackning	Tillverkningsdag	Används innan	Temperatur-gränser	Temperaturgränser för användning
HR	Usklađenost s EU zahtjevima	Proizvođač	Kataloški broj	Broj serije	Komada u kutiji/pakiranju	Datum proizvodnje	Rok valjanosti	Granice temperature	Granice radne temperature
PL	Zgodność Europejska	Wyprodukowany przez	Numer katalogu	Numer partii	Liczba sztuk w opakowaniu	Data Produkcji	Używać w terminie do	Wartości graniczne temperatury	Temperatura operacyjna
CS	Evropská shoda	Vyrobeno v	Katalogové číslo	Šarže	Kusů v krabici/balení	Datum výroby	Použitelné do	Meze teploty	Meze provozní teploty

								
Limiti di Umidità	Tenere al riparo dalla luce solare	Teme l'umidità	Attenzione leggere attentamente la documentazione allegata	Consultare le istruzioni d'uso	Non riutilizzare	Non contiene LATTICE di gomma naturale	Compatibile con Corpuls3 (Defib-Unit con pad riusabili)	Non usare con Corpuls3 con Defib-Unit SLIM
Humidity limits	Keep away from sun light	Keep away from humidity	Warning: read the enclosed documentation	Consult instructions for use	Do not reuse	Latex free	Compatible with Corpuls3 (Defib-Unit with reusable pads)	Do not use with Corpuls3 with Defib-Unit SLIM
Limites d'humidité	Protéger des rayons du soleil	Craint l'humidité	Attention lire attentivement la documentation ci-jointe	Consulter les instructions	Ne pas réutiliser	Ne contient pas de latex de caoutchouc naturel	Compatible avec Corpuls3 (Defib-Unit avec pad réutilisables)	Ne pas utiliser avec Corpuls3 avec Defib-Unit SLIM
Feuchtigkeits-begrenzungen	Vor Sonne schützen	Vor Feuchtigkeit schützen	Warnzeichen: lesen Sie die Beschreibung	Gebrauchsanweisung lesen	Einmalgebrauch	Latexfrei	Kompatibel mit Corpuls3 (Defib-Unit mit wiederverwendbaren Pads)	Nicht mit Corpuls3 mit Defib-Unit SLIM verwenden
Vochtigheidsgrens	Tegen zonnelicht beschermen	Niet bestand tegen vochtigheid	Let op, lees zorgvuldig de bijgesloten documentatie	Lees eerst de instructies	Niet her te gebruiken	Bevat geen natuurrubber	Compatibel met Corpuls3 (Defib-Unit met hergebruikbaar pad)	Niet gebruiken met Corpuls3 met Defib-Unit SLIM
Limites de humedad	Mantener lejos de la luz solar	Mantener lejos de la humedad	Alerta: lea la documentación adjunta	Consulte las instrucciones de uso	No reutilizar	Libre de látex	Compatible con Corpuls3 (Defib-Unit con pad reusables)	No usar con Corpuls3 con Defib-Unit SLIM
Limites de Humidade	Manter protegido da luz do sol	Teme a humidade	Atenção, ler atentamente a documentação incluída	Consultar instruções de utilização	Não reutilizar	Não contém látex de borracha natural	Compatível com Corpuls3 (Defib-Unit com placas reutilizáveis)	Não usar com Corpuls3 com Defib-Unit SLIM
Ограничения по влажности	Оберегать от солнечных лучей	Оберегать от влаги	Внимание: прочитайте прилагаемую документацию	Обратитесь к инструкции по применению	Не использовать повторно	Не содержит латекса	Совместим с Corpuls3 (Defib-Unit с многоразовыми пластинами)	Не использовать с Corpuls3 с Defib-Unit SLIM
Επίπεδα Υγρασίας	Μακριά από φως	Μακριά από υγρασία	Προειδοποίηση	Συμβουλευτείτε τις οδηγίες χρήσης	Να μην ξαναχρησιμοποιηθεί	Χωρίς λάτεξ	Συμβατό με Corpuls3 (Defib-Unit με pad επαναχρησιμοποιήσιμα)	Δε χρησιμοποιείται με Corpuls3 με Defib-Unit SLIM
Fuktighetsgränser	Skyddas mot solljus	Skyddas mot väta	Varning: läs den bifogade bruksanvisningen	Läs bruksanvisningen	Endast för engångsbruk	Latexfri	Kompatibel med Corpuls3 (Defib-enhet med återanvändbar dyna)	Använd inte med Corpuls3 med Defib-enhet SLIM
Granice vlažnosti	Držati podalje od izvora sunčevog svjetla	Držati na suhom mjestu	Upozorenje:prouči te priloženu dokumentaciju	Pročitajte upute za upotrebu	Za jednokratnu upotrebu	Ne sadrži latex	Kompatibilan sa Corpuls3 (Defib-Unit sa papučicom za višestruku primjenu)	Ne upotrebljavati sa Corpuls3 sa Defib-Unit SLIM
Wartości graniczne wilgotności	Przechowywać z dala od światła słonecznego	Chronić przed wilgocią	Uwaga dokładnie przeczytać załączoną dokumentację	Zapoznać się z instrukcją użytkowania	Nie używać ponownie	Nie zawiera LATEKSU z gumy naturalnej	Kompatybilny z Corpuls3 (Defib-Unit z podkładkami wielokrotnego użytku)	Nie używać z zastosowaniem Corpuls3 z Defib-Unit SLIM
Meze vlhkosti	Uchovávejte mimo sluneční záření	Uchovávejte v suchu	Varování: čtěte přiloženou dokumentaci	Věnujte pozornost návodu k použití	Nepoužívejte opakovaně	Bez latexu	Kompatibilní s Corpuls3 (Defibrilační jednotka s opakovaně použitelnými elektrodami)	Nepoužívejte s Corpuls3 a defibrilační jednotkou SLIM

progetti
Medical Equipment Solutions

DECLARATION OF EU CONFORMITY

DICHIARAZIONE DI CONFORMITA' EU

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 AND SUBSEQUENT AMENDMENTS

AI SENSI DELLA DIRETTIVA 93/42/CEE DEL 14 GIUGNO 1993 E SUE SEGUENTI MODIFICHE

CONCERNING MEDICAL DEVICES

RELATIVA AI DISPOSITIVI MEDICI

PRODUCT *Prodotto*	**Elettrodi Monouso Multifunzione per defibrillatore** *Disposable Multifunction Electrodes for defibrillator*
MODELS (**REF**) *Modelli*	**DFBAD01STD, DFBAD01PRC, DFBPED01PRC**
CND CODE *Codice CND*	**C020401**
GMDN / UMDNS CODE *Codice GMDN / UMDNS*	**47055**
CLASS *Classe*	**II b**
MANUFACTURER *Fabbricante*	**PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
APPLIED STANDARDS *Norme applicate*	**EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 60601-1:2006, EN 60601-1-2:2015, EN 60601-2-4:2011, EN 62366-1:2007, ISO 10993-5, ISO 10993-10, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
BATCH NUMBER (**LOT**) *Numero di lotto*	*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL **DIRECTIVE 93/42/EEC** OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, ACCORDING TO ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. ALSO, THE PRODUCT IS MANUFACTURED BASED ON **DIRECTIVE 2011/65/EEC (*ROHS*)** AND SUBSEQUENT AMENDMENTS. THE PRODUCT CONCERNED HAS BEEN MANUFACTURED UNDER A **QUALITY MANAGEMENT SYSTEM** ACCORDING TO **ANNEX II** OF **DIRECTIVE 93/42/EEC.**

*DICHIARIAMO QUINDI CHE IL PRODOTTO SOPRA SEGNALATO SODDISFA LA TRASPOSIZIONE IN DIRITTO NAZIONALE, LE DISPOSIZIONI DELLA **DIRETTIVA 93/42/CEE** DEL CONSIGLIO DEL 14 GIUGNO 1993 RELATIVA AI DISPOSITIVI MEDICI, SECONDO I REQUISITI ESSENZIALI E LE MODIFICHE SUCCESSIVE. TUTTA LA DOCUMENTAZIONE DI SUPPORTO È DISPONIBILE PRESSO IL FABBRICANTE. INOLTRE, IL PRODOTTO È REALIZZATO IN BASE ALLA DIRETTIVA **2011/65/CEE (ROHS)** E SUCCESSIVE MODIFICHE. IL PRODOTTO IN OGGETTO È STATO REALIZZATO AI SENSI DI UN **SISTEMA DI GESTIONE DELLA QUALITÀ** SECONDO L'**ALLEGATO II** DELLA **DIRETTIVA 93/42/CEE**.*

NOTIFIED BODY *Ente Notificato*	MTIC InterCert S.r.l. (Notified Body N°**0068**) Via Moscova, 11 20017 Rho (MI)- ITALY
EC MARKING *Marcatura CE*	CE 0068
EC CERTIFICATE N° *Certificato CE n°*	**0068/QCO-DM/004-2015 Rev.01**
EXPIRE DATE OF EC CERTIFICATE *Data di scadenza del certificato CE*	**27/05/2024**
FIRST ISSUE DATE OF EC CERTIFICATE *Data di prima emissione del certificato CE*	06/05/2015
PLACE AND DATE OF ISSUE *Luogo e Data di emissione*	TROFARELLO (TO), 01/02/2021
SIGNATURE *Firma*	Dr. CESARE MANGONE MANAGEMENT REPRESENTATIVE

*IF YOU WANT RECEIVE DEDICATED DECLARATION OF CONFORMITY FOR YOUR DEVICE BATCH NUMBER
*PER RICEVERE LA DICHIARAZIONE DI CONFORMITA' DEDICATA ALLO SPECIFICO **NUMERO DI LOTTO***
AND/OR UPDATED ONE, PLEASE CONTACT PROGETTI S.R.L. OFFICE TO THE EMAIL info@progettimedical.com
E/O UN AGGIORNAMENTO, SI PREGA DI CONTATTARE PROGETTI S.R.L. ALL'INDIRIZZO EMAIL info@progettimedical.com