



# BC "MOLDINDCONBANK" S.A.

## Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chișinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDMD2X329

Data 14. IAN. 2016  
Nr. 03/2 - 19/23

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московской, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea cu Răspundere Limitată "BIOSISTEM MLD"**  
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

*Numărul de identificare de stat - codul fiscal*  
**1010600028048**

*Data înregistrării*

**12.08.2010**

*Data eliberării*

**12.08.2010**

**Svirepova Ludmila, registrator**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*L. Svirepova*  
semnătura

**MD 0101250**







**I.P. "AGENȚIA SERVICII PUBLICE"**

Departamentul înregistrare și licențiere a unităților de drept

**EXTRAS**

**din Registrul de stat al persoanelor juridice**

**nr. 8506 din 28.04.2021**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

**Administrator: POIATA VITALIE,**

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator  
tel. 022-207-840



**Lazari Aliona**



**EB 0358735**



## **Lista fondatorilor Biosistem-mld SRL**

<b>Nr.</b>	<b>Nume, Prenume</b>	<b>IDNP</b>
<b>1.</b>	<b>Vitalie Poiata</b>	<b>0983103892591</b>
<b>2.</b>	<b>Alexandr Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

# DECLARATION OF CONFORMITY

Forlì, 5<sup>th</sup> August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **TOP TRACE ECG ELECTRODES (BASIC UDI-DI 8059170EL001PR)**, identified and classified in the technical file, declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

In addition:

- the device is tested according to the voluntary Association for the Advancement of Medical Instrumentation (AAMI) standard requirements for electrical performance for disposable ECG electrodes (ANSI/AAMI EC 12:2000) and test results meet or exceed these performance standards.
- the device is tested and it is found to be acceptable for use, according to:

UNI EN ISO 10993-1: "Biological evaluation of medical devices" ;

UNI EN ISO 10993-5 : "Biological evaluation of medical devices :tests for in vitro cytotoxicity";

UNI EN ISO 10993-10 : "Biological evaluation of medical devices :tests for irritation and sensitization".

- Ceracarta does not use any latex/PVC materials or ingredients in the manufacturing of our electrodes;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA  
Bandini Alessandro



**TOP**  
**TRACE**

**NM 55 RLI**

**MONITORING ECG ELECTRODES**



Support	FOAM	Gel	LIQUID gel
Diameter	55 mm.	Sensor material	Ag/AgCl
Reorder cod.	14709	Manufacturer	CERACARTA SpA

TECHNICAL DATA			
Product profile		Electric features	
Disposable ECG electrode, white FOAM type diam. 55mm. Circular shaped, centered snap with conductive liquid gel column. Aggressive medical grade adhesive. Liquid gel electrodes utilize non-irritating Potassium Chloride gel to provide fast signal response with low impedance. The large surface area of it offers improved adhesion leading to cleaner traces.		DC offset Voltage	0,12 mV
Features	It is manufactured out of an aggressive, non-sensitizing, acrylic copolymer coated foam. All electrodes are Latex-free.	AC Impedance 10 Hz	60 (OHMS)
Benefits	This hypoallergic, non-irritating, disposable electrode meets and exceeds all AAMI performance specs.	DC Offset 5 sec after capacitor discharge	6,5 (Mv)
Applications	Specially designed for the difficult adhesion conditions that occur in patient standard monitoring	Recovery Slope 30 second interval	0,0 (mV/sec)
Performance Charact.	The electrode incorporates Potassium Chloride gel and is tested according to the voluntary Association of the Advancement of Medical Instrumentation (AAMI), USA	AC Impedance after defibrillation	46 (OHMS)
Packaging	25 pcs / Aluminium envelopes 500 pcs/ Box 6,000 pcs / Master carton	Compliance to standards: Directive 93/42/Eec (D.L.46/97). Class I device Product branded CE	

## RUBBER LIMB & THORACIC STRAPS



For attaching electrodes • the special “anti-aging” treatment retards the crystallization of the rubber when exposed to the sun or air • available in different sizes: for limbs use - one hole (15 mm x 40 cm / 25 mm x 45 cm), - two holes (32mm x 45cm) - for thoracic use - one hole (32mm x 135cm), six holes (100mm x 135cm).

## ELECTRODES FOR TENS AND EMG



• Superior quality • available with a single or double helix • free terminal lead wires or with safety CAP • individual bags - package with 50 bags • manufactured in compliance with EN ISO 9001 and AAMI standards.

## ELECTRO SURGICAL PLATES



• Made of FOAM suitable to obtain perfect results with all instruments • manufactured and tested in compliance with EN 60601-1/ EN 60601-2/ AAMI-HF 18 • available with one zone and two zones and REM alarm for adults (adhesive surface 215 sq cm), for children (surface 129 sq cm) and for new born (surface 63 sq cm). **All the models are available even equipped with cables.**

## DEFIBRILLATION PADS



Produced using a high quality material • flexible foam • bio-compatible akrylic adhesive • conductive hydrogel • maintain a stable conductivity to temperature, humidity and time • avoid the direct contact between metal paddles and patient's skin • do not contaminate the metal paddles and do not corrupt future defibrillations • packing: 2pads/ bag - 50 pads/ box.

## PULSE OXIMETER SENSORS



A broad range of sensors to monitor and detect the arterial oxygen saturation. Excellent quality and proven accuracy are the characteristics that better describe a whole series of disposable and reusable sensors. Suitable for all the main fittings spread on the market and perfectly matching with adults/ children and newborn needs, these sensors do ensure the best performance and the top reliability.





## ELECTRODES &amp; ACCESSORIES FOR EEG &amp; EMG

A serie of high quality/ performing EEG-EP accessories enrich our range:

**A) BRIDGE ELECTRODES** Made of silver/ silver chloride to optimize signal transmission. Available in three colours (red, blue, yellow)- Slightly curved support to improve head adaption. Three different types of connection (horizontal, vertical, with clamp electrode);

**B) SILICONE HEADCAPS** With 2 or 4 adjustable bands to fit for various requirements. Anatomically-designed earmuffs. Available in three sizes (Small-Medium-Large);

**C) SPECIAL INK FOR EEG** Suitable & excellent for all devices (Siemens excluded), allowing a perfect trace without blurs. Black colour- 1 litre bottle with graduated scale- (6 bottles per box- 4 boxes per carton);

**D) DISK ELECTRODES** Available in silver/ silver chloride or gold - 10 mm diameter- With 120-150-200-250 cm lead wire & DIN 42802 safety plug - 10 electrodes per set with coloured lead wires (available 10 colours);

**E) DISPOSABLE CONCENTRIC NEEDLES FOR ELECTROMYOGRAPHY** Easy to use thanks to an ergonomic handgrip and an extremely sharp point - Recording area marker - Equipped with wings for automatic unfastening -Shielded, light & flexible lead wire with 5 pole DIN 45322 connector and entirely shielded handgrip. Available in different diameters (from 0.35 to 0.60 mm) and different lengths (from 20 to 70 mm) - 50 pcs per packing.



## MOUTHPIECES

Made of material particularly resistant to saliva or manipulation, perfectly hygienic, without residues and non-allergic - can be used on most spirometers of the most important brands present on the market - available in the external diameters 22-26-28-30 and 34 mm, but in the case of large orders the customer can request a specific diameter - boxes of 500 pieces - an extremely handy dispenser is available on customer's demand.

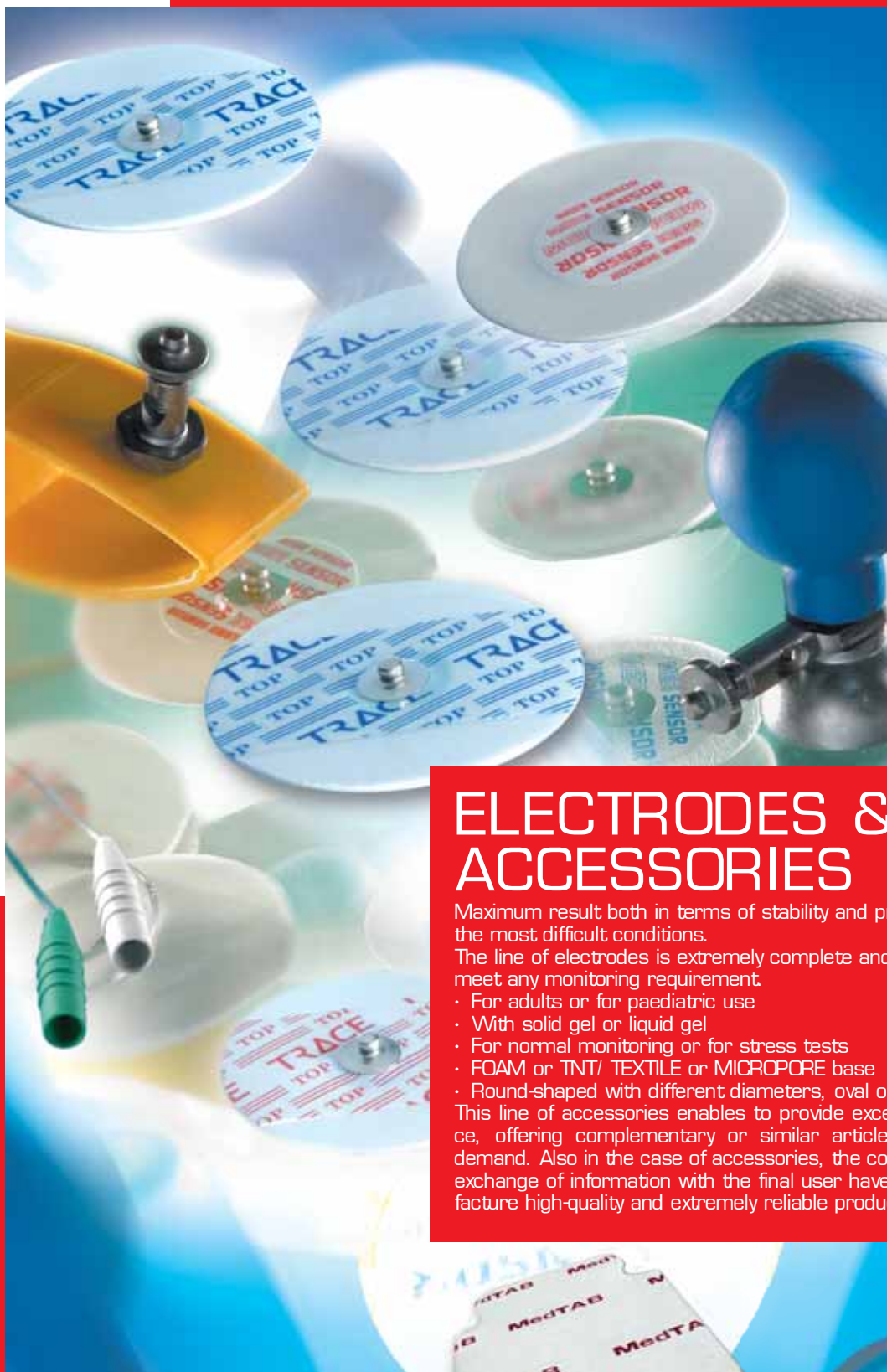


EC product compliance



COMPANY WITH QUALITY MANAGEMENT  
SYSTEM CERTIFIED BY DNV  
= ISO 9001:2008 =  
ISO 13485:2003

Via Secondo Casadei N.14  
zona industriale Villa Selva - 47122 Forlì (Italy) tel. +39.0543.780055 - fax +39.0543.781404  
www.ceracarta.it - e mail: export@ceracarta.it



## ELECTRODES & ACCESSORIES

Maximum result both in terms of stability and precision, also under the most difficult conditions.

The line of electrodes is extremely complete and makes it possible to meet any monitoring requirement.

- For adults or for paediatric use
- With solid gel or liquid gel
- For normal monitoring or for stress tests
- FOAM or TNT/ TEXTILE or MICROPORE base
- Round-shaped with different diameters, oval or rectangular

This line of accessories enables to provide excellent customer service, offering complementary or similar articles that are in great demand. Also in the case of accessories, the continuous research and exchange of information with the final user have allowed us to manufacture high-quality and extremely reliable products.



# CERACARTA





# TOP TRACE LINE FOR NORMAL MONITORING



## NM 50 RFI

Ø50 mm.	<b>Dimensions</b>	Ø50 mm.
Foam	<b>Backing</b>	TNT
Solid	<b>Gel</b>	Solid
Ag/AgCl	<b>Sensor</b>	Ag/AgCl

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

### Packaging

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

The most typical sizes. The most demanded supports. A proved quality always useful.



## NM 50 TNI



## NM 42 DFI

45x42 mm.	<b>Dimensions</b>	42x36 mm.
Foam	<b>Backing</b>	Foam
Solid	<b>Gel</b>	Solid
Ag/AgCl	<b>Sensor</b>	Ag/AgCl

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

### Packaging

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

Two multifunctional models: suitable for adult and pediatric ECG's (low stock availability - smallscale investment).



## NM 3642 OFI



## NP 30 RFI

Ø30 mm.	<b>Dimensions</b>	23x34 mm.
Foam	<b>Backing</b>	Silicone coated pet film
Solid	<b>Gel</b>	Solid
Ag/AgCl	<b>Sensor</b>	Ag/AgCl

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

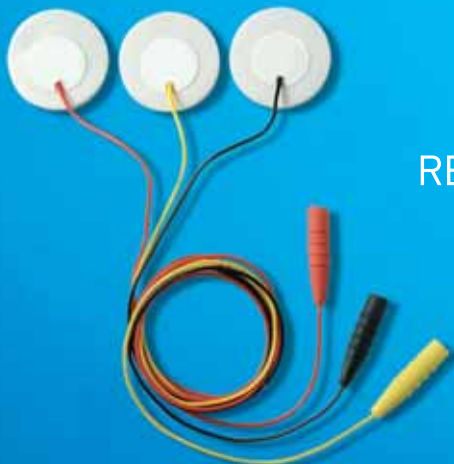
The classical and largely used electrode for pediatric ECG's. Excellent quality ensured also on "critical" patients.

## MED TAB



100 pcs / pouch - 500 pcs / box - 5000 pcs / carton

This electrode entirely replaces suction chests and clamps to patient's advantage both in terms of hygiene and health.



## RE 30 LWF

30 mm. female 4 mm	<b>Dimensions</b>	22 mm. safety 1,55 mm
Foam	<b>Backing</b>	Foam
Solid	<b>Gel</b>	Solid
Ag/AgCl	<b>Sensor</b>	Ag/AgCl

3 pcs / pouch - 120 pcs / box

Available also with 22 mm diameter Model RE 22 LWF (with 4 mm female plug)



## RE 22 LWS

3 pcs / pouch - 120 pcs / box

Available also with 30 mm diameter Model RE 30 LWS (with 1,55 mm safety plug)



# TOP TRACE LINE FOR STRESS TEST & HOLTER



## ST 50 RFI

Ø 50 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

### Packaging

## ST 50 RLI



Ø 50 mm.

Foam

Liquid

Ag/AgCl

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

The most suitable electrodes for ECG's under difficult conditions.

Easy to apply and use • Strong adhesiveness • Do not irritate the skin • Highly conductive gel



## NM 55 RLI

Ø 55 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Liquid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

25 pcs / pouch - 500 pcs / box - 6000 pcs / carton

### Packaging

## NM 55 TNI



Ø 55 mm.

TNT

Solid

Ag/AgCl

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

When a larger adhesive surface is mandatory for an excellent examination.

Easy to apply and use • Strong adhesiveness • Do not irritate the skin • Highly conductive gel

## TOP TRACE LINE RADIOTRANSSPARENT



## RT 50 RFI FOR ADULT USE

Ø 50 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

### Packaging



## RT 30 LWF

30 mm. female 4 mm	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

3 pcs / pouch - 120 pcs / box

### Packaging

Available also with 22 mm diameter Model RT 22 LWF  
(with 4 mm female plug)

## TOP TRACE LINE BANANA CONNECTOR

## NM 2844 FBI

**Dimensions** 28x44 mm.

**Backing** Foam

**Gel** Solid



## RT 22 LWS

22 mm.  
safety 1,55 mm

Foam

Solid

Ag/AgCl

3 pcs / pouch - 120 pcs / box



Available also with 30 mm diameter Model RT 30 LWS  
(with 1,55 mm safety plug)



**MODEL F 50**  
FOR NORMAL  
MONITORING

Ø 50 mm.

**Dimensions**

Foam

**Backing**

Liquid

**Gel**

**MODEL F55**  
FOR NORMAL  
MONITORING

Ø 55 mm.

Foam

Liquid



**New!**



**MODEL FS50**  
FOR STRESS TEST

Ø 50 mm.

**Dimensions**

Foam

**Backing**

Liquid

**Gel**

**MODEL W 601 L**  
FOR HOLTER/  
LONG MONITORING

Ø 55 mm.

TNT

Liquid



**TOP RESULTS FOR STRESS TEST**

**TOP RESULTS FOR HOLTER**

## CLAMP ELECTRODES



The classical-designed clamps but with an improved quality. Composed of 3 pieces with sensors in silver/silver chloride for maximum reliability in signal transmission.

### NEW DESIGN:

The structure consists of a single piece (all other clamps are made up of three pieces) to avoid breaking. • Possibility of opening the clamps more than usual in the case of particularly strong limbs. • This means that the product is practically indestructible and extremely versatile.

### SILVER / SILVER CHLORIDE SENSORS:

For maximum reliability in signal transmission. • only silver can prevent changes, distortions and disturbances which might occur with other metals; therefore the clamps are completely efficient. • only silver allows for full recovery after defibrillation as required by AAMI standards.

### UNIVERSAL CONNECTION

suitable for any product type

SET OF FOUR CLAMPS in yellow, green, red and black

THE CLAMP ELECTRODES ARE AVAILABLE ALSO IN THE PEDIATRIC VERSION WITH THE SAME STRUCTURAL AND SENSORIAL CHARACTERISTICS AS THOSE FOR ADULTS

## SUCTION CUP ELECTRODES



**3 SIZES**



THE SUCTION CUP ELECTRODES ARE AMONG THE BEST YOU CAN FIND ON THE MARKET TODAY

- SILVER / SILVER CHLORIDE CUP SENSOR, GUARANTEES MAXIMUM RELIABILITY IN SIGNAL TRANSMISSION, PREVENTS DISTORTIONS AND DISTURBANCES. IN PARTICULAR IT ALLOWS FOR FULL RECOVERY AFTER DEFIBRILLATION.
- SUCTION CUP MADE OF A SPECIAL MIXTURE WHICH IS VERY SOFT AND THEREFORE EXTREMELY USEFUL TO CREATE A VACUUM AS WELL AS BEING VERY STRONG AND ABSOLUTELY NON-DEFORMING EVEN AFTER BEING USED THOUSANDS OF TIMES.
- UNIVERSAL CONNECTION SUITABLE FOR ANY CONNECTION TYPE
- AVAILABLE IN THREE VERSIONS: FOR PAEDIATRIC USE WITH A 15 MM DIAMETER AND FOR USE ON ADULTS WITH 24 MM AND 30 MM DIAMETERS.