

ORDIN DE PLATA NR.: 1102

TIP.DOC. 1

DATA EMITERII:30 decembrie 2021

PLATITI: 500-00

LEI: Cinci Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM  
MLD" SRL

CONTUL DE PLATI/CODUL IBAN  
MD95ML000000002251429243  
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR  
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:  
:MOLDMD2X329

BENEFICIAR (R)IMSP Spital  
Clinic RepublicanTimofei Mosn  
eaga

CONTUL DE PLATI/CODUL IBAN  
MD32ML000000002251502448  
CODUL FISCAL :1003600150783 /

PRESTATORUL BENEFICIAR  
BC"Moldindconbank"S.A.

CODUL BANCII:  
:MOLDMD2X

DESTINATIA PLATII:Pentru garantia pentru:  
oferta la procedura de achizi?ie public:  
a nr. ocde-b3wdp1-MD-1637761078234 din 0:  
1.01.2022

TIPUL TRANSFERULUI  
NORMAL/URGENT :N

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:30/12/2021  
DATA EXECUTARII:

SEMNATURILE  
EMITENTULUI

CONDUCATOR:Web Poiata Vitalie  
MIIGYwYJKoZIhvcNAQcCoIIIGVDCCB1ACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3

DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqG

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DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTA1EMRA:  
gYDVQQIEwdNb2xkb3ZHMREwDwYDVQQHEWhDaGZaw5hdTEWMBQGA1UEChMNQm1

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIIGVDCCB1QCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:  
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L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

Digitally signed by Poiata Vitalie  
Date: 2021.12.30 15:33:46 EET  
Reason: MoldSign Signature  
Location: Moldova



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ORDIN DE PLATA NR.: 1103 TIP.DOC. 1 :  
DATA EMITERII:30 decembrie 2021 :  
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PLATITI: 4500-00 LEI: Patru Mii Cinci Sute lei 00 ba :  
ni :  
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PLATITOR: (R) 'BIOSISTEM CONTUL DE PLATI/CODUL IBAN :  
MLD" SRL MD95ML000000002251429243 :  
CODUL FISCAL :1010600028048 / :  
-----

PRESTATORUL PLATITOR CODUL BANCII :  
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329 :  
=====

BENEFICIAR (R)IMSP Spital CONTUL DE PLATI/CODUL IBAN :  
Clinic RepublicanTimofei Mosn MD32ML000000002251502448 :  
eaga CODUL FISCAL :1003600150783 / :  
-----

PRESTATORUL BENEFICIAR CODUL BANCII :  
BC"Moldindconbank"S.A. :MOLDMD2X :  
=====

DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :  
oferta la procedura de achizi?ie public: NORMAL/URGENT :N :  
a nr. ocds-b3wdp1-MD-1637761078234 din 0: :  
1.01.2022 :  
: :  
: L.S. :  
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CODUL TRANZACTIEI:001: :  
DATA PRIMIRII:30/12/2021 : SEMNATURILE :  
DATA EXECUTARII: : EMITENTULUI :  
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CONDUCATOR:Web Poiata Vitalie :  
MIIGyWYJKoZiHvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB :  
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq :  
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(semnatura electronica) :  
CONTABIL-SEF:Web Nasedchin Alexandr :  
MIIGZwYJKoZiHvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3 :  
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L.S. (semnatura electronica) :  
CONDUCATOR: :  
(semnatura manuala) :  
CONTABIL-SEF: :  
(semnatura manuala) :  
SEMNATURA PRESTATORUL L.S. :  
-----

MOTIVUL REFUZULUI : L.S. :  
-----



# 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> |

# Titanium Ligation System

## LigaV<sup>®</sup> ligating clips & clip applicators

**Reliable Ligation**



PROVIDING SPECIALISTS WITH  
**INNOVATIVE**  
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON  
**PATIENTS' SAFETY** AND USERS' COMFORT

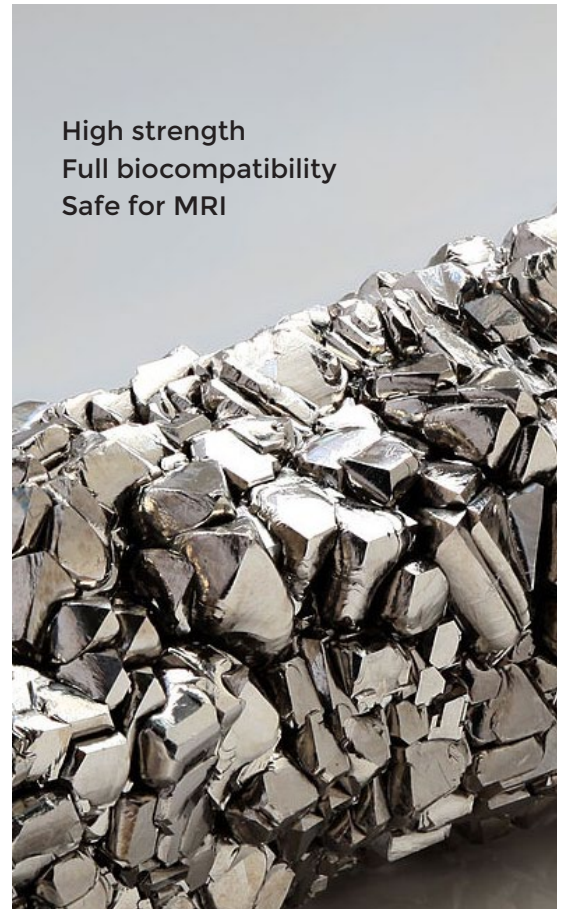


## LigaV<sup>®</sup> ligating clips

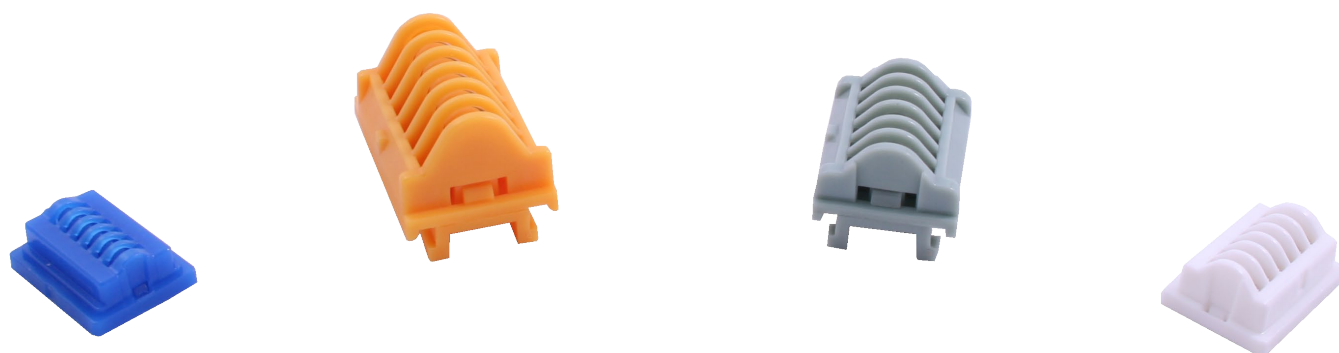
LigaV<sup>®</sup> Ligating Clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features. LigaV<sup>®</sup> manufactured by Grena Ltd., comes with inner and outer serration which enhances its function. The outer serration helps to grip the clip in the applicator's jaws; the inner serration enables its proper nourishment. The product is offered in 4 standard sizes ensuring every user will be able to find appropriate clip for the given tissue. The LigaV<sup>®</sup> clips are delivered in colour coded cartridges to ensure easy and intuitive identification. A cartridge includes 4, 6 or 20 clips that ensure economical and comfortable use. The product is disposable, EO sterilized. Clip applicators with proper sized jaws depending on the clip should be used. Clip applicators are made of highest quality surgical grade steel. Handle rings are color coded matching cartridge hue.

### KEY FEATURES:

- 4 sizes available: S, M, ML, L
- 4, 6 or 20 clips per cartridge
- V-shaped
- Made of a medical grade titanium,
- Color-coded cartridges for easy identification
- Compatible with corresponding Vclip<sup>®</sup> Applicators



| REF         | CLIP SIZE    | COMPATIBLE WITH APPLIERS (JAWS GRIP) (MM) | PRODUCT                          | COLOUR | PCS PER CARTRIDGE/ BOX |
|-------------|--------------|-------------------------------------------|----------------------------------|--------|------------------------|
| 0301-01S    | Small        | 0,59-0,75                                 | V-shaped titanium ligating clips | ●      | 6/50                   |
| 0301-01S20  | Small        | 0,59-0,75                                 | V-shaped titanium ligating clips | ●      | 20/14                  |
| 0301-01M    | Medium       | 0,84-1,00                                 | V-shaped titanium ligating clips | ○      | 6/50                   |
| 0301-01M20  | Medium       | 0,84-1,00                                 | V-shaped titanium ligating clips | ○      | 20/14                  |
| 0301-01ML   | Medium-Large | 1,16-1,32                                 | V-shaped titanium ligating clips | ●      | 6/20                   |
| 0301-01ML04 | Medium-Large | 1,16-1,32                                 | V-shaped titanium ligating clips | ●      | 4/20                   |
| 0301-01L    | Large        | 1,26-1,42                                 | V-shaped titanium ligating clips | ●      | 6/20                   |



**4 CLIPS PER CARTRIDGE**  
Cost-effective alternative  
for simple procedures

## LigaV<sup>®</sup> open surgery clip appliers

LigaV<sup>®</sup> open surgery appliers are available in a wide range of sizes and applier lengths. Made of the highest quality surgical stainless steel to meet the requirements of the most demanding professionals. Handle rings are color-coded matching cartridge hues.

### KEY FEATURES:

- Available for Small, Medium, Medium-Large and Large non-absorbable LigaV<sup>®</sup> clips to be used on large spectrum of tissue sizes
- 3 lengths available: 15 cm, 20 cm and 28 cm
- Made of high quality surgical stainless steel
- Colour-coded rings matching cartridge hue



| REF         | CLIP SIZE    | TYPE         | APPLIER LENGTH (CM) | COLOUR | PCS PER BOX |
|-------------|--------------|--------------|---------------------|--------|-------------|
| 0301-02S15* | Small        | Open Surgery | 15                  | ●      | 1           |
| 0301-02S20  | Small        | Open Surgery | 20                  | ●      | 1           |
| 0301-02S28* | Small        | Open Surgery | 28                  | ●      | 1           |
| 0301-02M15* | Medium       | Open Surgery | 15                  | ○      | 1           |
| 0301-02M20  | Medium       | Open Surgery | 20                  | ○      | 1           |
| 0301-02M28* | Medium       | Open Surgery | 28                  | ○      | 1           |
| 0301-02ML20 | Medium-Large | Open Surgery | 20                  | ●      | 1           |
| 0301-02ML28 | Medium-Large | Open Surgery | 28                  | ●      | 1           |
| 0301-02L20  | Large        | Open Surgery | 20                  | ●      | 1           |
| 0301-02L28  | Large        | Open Surgery | 28                  | ●      | 1           |

\* Manufactured on request.

Other lengths and jaw's angles available on request.



## Omnifinger™ articulating endoscopic clip appliers

Omnifinger™ is an outstanding articulating endoscopic clip applier designed to deal with challenging cases. This innovative tool offers some unique features that can help surgeons to open the doors to new operating techniques.

### KEY FEATURES:

- 60° of total angulation
- Articulation and 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel



| REF            | SIZE | LOCK | COLOUR | SHAFT DIAMETER (MM) | TROCAR DIAMETER (MM) | WORKING LENGTH (CM) | BOX QUANTITY (PCS) |
|----------------|------|------|--------|---------------------|----------------------|---------------------|--------------------|
| 0301-02MEOMN   | M    | YES  | ○      | 10                  | 10                   | 36                  | 1                  |
| 0301-02MLEOMN  | ML   | YES  | ●      | 10                  | 10                   | 36                  | 1                  |
| 0301-02LEOMN   | L    | YES  | ●      | 12                  | 12                   | 36                  | 1                  |
| 0301-02MEOMNB  | M    | YES  | ○      | 10                  | 10                   | 47                  | 1                  |
| 0301-02MLEOMNB | ML   | YES  | ●      | 10                  | 10                   | 47                  | 1                  |
| 0301-02LEOMNB  | L    | YES  | ●      | 12                  | 12                   | 47                  | 1                  |

## LigaV<sup>®</sup> endoscopic clip appliers

LigaV<sup>®</sup> endoscopic clip appliers are available in a wide range of sizes. Made of the highest quality surgical stainless steel Grena appliers guarantees ergonomic and effective approach in endoscopic procedures.

Handle rings are color-coded matching cartridge hues. Precise performance makes Grena appliers the leading choice for surgeons performing endoscopic procedures.

### KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality stainless steel
- Non-detachable design for easier maintenance and durability



| REF        | CLIP SIZE    | TYPE       | WORKING LENGTH (CM) | SHAFT DIAMETER (MM) | COLOUR | PCS PER BOX |
|------------|--------------|------------|---------------------|---------------------|--------|-------------|
| 0301-02ME  | Medium       | Endoscopic | 33                  | 10                  | ○      | 1           |
| 0301-02MLE | Medium-Large | Endoscopic | 33                  | 10                  | ●      | 1           |
| 0301-02LE  | Large        | Endoscopic | 33                  | 10                  | ●      | 1           |

## LigaV<sup>®</sup> endoscopic clip appliers 45 cm

In order to carry out bariatric procedures safely, Grena offers extra length endoscopic clip appliers for bariatric surgery.

### KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality stainless steel
- Non-detachable design for easier maintenance and durability
- Colour-coded rings matching cartridge hue
- Available length: 45 cm



| REF         | CLIP SIZE    | TYPE       | WORKING LENGTH (CM) | SHAFT DIAMETER (MM) | COLOUR | PCS PER BOX |
|-------------|--------------|------------|---------------------|---------------------|--------|-------------|
| 0301-02MEB  | Medium       | Endoscopic | 45                  | 10                  | ○      | 1           |
| 0301-02MLEB | Medium-Large | Endoscopic | 45                  | 10                  | ●      | 1           |
| 0301-02LEB  | Large        | Endoscopic | 45                  | 10                  | ●      | 1           |

## LigaV<sup>®</sup> endoscopic clip appliers 25°

### KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability
- Colour-coded rings matching cartridge hue
- Jaws angle 25°



| REF           | CLIP SIZE    | TYPE       | WORKING LENGTH (CM) | SHAFT DIAMETER (MM) | COLOUR | PCS PER BOX |
|---------------|--------------|------------|---------------------|---------------------|--------|-------------|
| 0301-02MLEA25 | Medium-Large | Endoscopic | 33                  | 10                  | ●      | 1           |



### Grena Ltd.

1000 Great West Road,  
Brentford, London TW8 9HH,  
United Kingdom

**LONDON** *of* **CHAMBER**  
COMMERCE AND INDUSTRY

### CUSTOMER SERVICE CENTER

NOTTINGHAM OFFICE, UK

☎ + 44 115 9704 800

☎ + 44 115 9704 800

✉ [export@grena.co.uk](mailto:export@grena.co.uk)

[www.grena.co.uk](http://www.grena.co.uk)





Brentford 23.04.2012

## TECHNICAL PARAMETERS OF GRENA TITANIUM AND POLYMER LIGATING CLIPS

### LigaV

| REF                                                     | S            | M            | ML           | L            |
|---------------------------------------------------------|--------------|--------------|--------------|--------------|
| Clip shape in the cartridge                             | V shaped     | V shaped     | V shaped     | V shaped     |
| Opened clip length (outer) after loading into applier   | 3,20 mm      | 4,70 mm      | 8,00 mm      | 11,90 mm     |
| Opened clip width (internal) after loading into applier | 2,10 mm      | 2,90 mm      | 5,20 mm      | 5,40 mm      |
| Closed clip length                                      | 3,70 mm      | 5,40 mm      | 9,00 mm      | 12,30 mm     |
| Recommended tissue thickness                            | 0,30-1,50 mm | 1,00-2,50 mm | 2,50-4,00 mm | 3,50-7,50 mm |

### Vclip

| REF                                                     | XS             | S              | M              | ML             | L              |
|---------------------------------------------------------|----------------|----------------|----------------|----------------|----------------|
| Clip shape in the cartridge                             | Chevron shaped | Chevron shaped | Chevron shaped | Chevron shaped | Chevron shaped |
| Opened clip length (outer) after loading into applier   | 2,25 mm        | 3,20 mm        | 5,30 mm        | 8,10 mm        | 11,00 mm       |
| Opened clip width (internal) after loading into applier | 1,80 mm        | 2,00 mm        | 3,30 mm        | 5,30 mm        | 7,70 mm        |
| Closed clip length                                      | 2,65 mm        | 3,70 mm        | 6,00 mm        | 9,10 mm        | 12,50 mm       |
| Recommended tissue thickness                            | 0,15-0,30 mm   | 0,30-1,50 mm   | 1,00-2,50 mm   | 2,50-4,00 mm   | 3,50-7,50 mm   |

### Click'aV

| REF                                      | M                | ML               | L                | XL               |
|------------------------------------------|------------------|------------------|------------------|------------------|
| Clip shape in the cartridge              | Divergent curved | Divergent curved | Divergent curved | Divergent curved |
| Outer leg length                         | 7,00 mm          | 9,50 mm          | 13,00 mm         | 17,80 mm         |
| Clip leg thickness                       | 0,83 mm          | 0,83 mm          | 1,29 mm          | 1,29 mm          |
| Retention bosses diameter                | 1,00 mm          | 1,10 mm          | 1,20 mm          | 1,30 mm          |
| Recommended tissue thickness             | 2 - 7 mm         | 3 - 10 mm        | 5 - 13 mm        | 7 - 16 mm        |
| Hinge type                               | Living hinge     | Living hinge     | Living hinge     | Living hinge     |
| Retention bosses distance in the applier | 5,50 mm          | 7,50 mm          | 10,20 mm         | 14,00 mm         |

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60147050 0001

**Report No.:** 26300270 016

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products:** (see attachments for products and site included)  
Replaces approval, registration no.: HD 60100981 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-02-25

**Date:** 2020-02-25



**Notified Body**

  
Sebastian Mnisek

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60147050 0001  
**Report No.:** 26300270 016

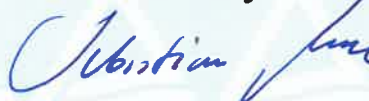
**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products included)**

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers
- Staples cartridge for reusable linear cutting staplers
- Ligating clip cartridge to be used with reusable automatic clip appliers

**Date: 2020-02-25**

**Notified Body**



**Sebastian Mniszek**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60147050 0001  
**Report No.:** 26300270 016

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

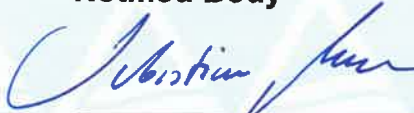
**Site included:**

Grena Limited  
Chelsea House, Chelsea Street  
Nottingham, NG7 7HP  
United Kingdom

**Activity:** Desing, development and manufacture

**Date:** 2020-02-25

**Notified Body**



**Sebastian Mniszek**





**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60147049 0001

**Report No.:** 26300270 017

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products:** (see attachments for products and site included)

Replaces EC Certificate, registration no.: DD 60100980 0001

**Expiry Date:** 2024-05-26

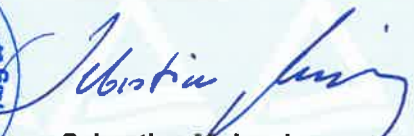
The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-02-25

**Date:** 2020-02-25



**Notified Body**

  
Sebastian Mniszek

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60147049 0001  
**Report No.:** 26300270 017

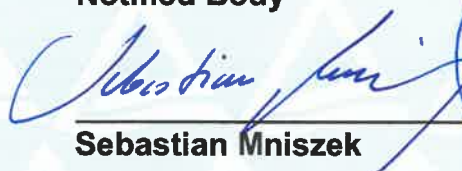
**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products included:**

- Disposable trocars
- Retrieval bags
- Veress needles
- Disposable wound protectors /retractors

**Date: 2020-02-25**

**Notified Body**

  
**Sebastian Mniszek**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60147049 0001  
**Report No.:** 26300270 017

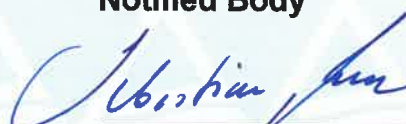
**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Site included:**

Grena Limited  
Chelsea House, Chelsea Street  
Nottingham, NG7 7HP  
United Kingdom

**Notified Body**

**Date: 2020-02-25**

  
**Sebastian Mniszek**



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1554225-1

Organization: GRENA Ltd.  
1000 Great West Road  
Brentford, MIDDLESEX  
TW8 9HH  
United Kingdom

Scope: Design and development, production and distribution of disposable  
and reusable medical devices for surgical and patient care procedures.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84952920-70  
Effective date: 2021-04-23  
Expiry date: 2022-04-13  
Issue date: 2021-04-23

  
  
Daniel Świątko  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1554225-1

Organization: GRENA Ltd.  
1000 Great West Road  
Brentford, MIDDLESEX  
TW8 9HH  
United Kingdom

The scope of certification includes the following additional sites:

| No. | Facility                                                                                | Scope                                                                                                                                                                                                                                                  |
|-----|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /01 | GRENA Ltd.<br>1000 Great West Road<br>Brentford, MIDDLESEX<br>TW8 9HH<br>United Kingdom | Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures.                                                                                                               |
| /02 | Grena Ltd.<br>Chelsea Street, Chelsea House<br>Nottingham<br>NG7 7HP<br>United Kingdom  | Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures.<br>Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices. |

Report No.: 84952920-70  
Effective date: 2021-04-23  
Expiry date: 2022-04-13  
Issue date: 2021-04-23

  
  
Daniel Swiątko  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



www.imq.it

**CERTIFICATO N.  
CERTIFICATE N. 9190.CRC3**

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

**CERACARTA SPA**

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

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

**ISO 9001:2008**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

*Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID).*

*Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione  
*Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization*

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

|              |                                                    |                                            |                           |
|--------------|----------------------------------------------------|--------------------------------------------|---------------------------|
| <b>DATE:</b> | <b>PRIMA CERTIFICAZIONE</b><br>FIRST CERTIFICATION | <b>EMISSIONE CORRENTE</b><br>CURRENT ISSUE | <b>SCADENZA</b><br>EXPIRY |
|              | 2002-11-26                                         | 2017-10-13                                 | 2020-10-07                |

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14;  
in caso contrario, il presente certificato cesserà la propria validità in tale data  
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14;  
otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07  
Data di conclusione dell'audit di rinnovo: 2017-10-11  
Data della decisione di rinnovo: 2017-10-13



IAF: 07, 09, 19, 29

SGQ N°005A, SGA N°006D, SCR N°005F,  
SSI N°003G, FSM N°007I, SGE N°006M,  
EMAS N°003P, PRD N°005B, PRS N°008C,  
ISP N°003E, LAB N°012I, LAT N°002I  
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento  
Processes related to underlined IAF sectors are not yet covered by accreditation  
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

Organismo di Certificazione Federato CISQ  
www.imq.it



CISQ is a member of



IO Net, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.  
IO Net is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.



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.





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/IMQ** as an IQNet Partner hereby states that the organization

## **CERACARTA SPA**

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC)

for the following scope:

**Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories**

*Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization*

has implemented and maintains a

## **Quality Management System**

which fulfills the requirements of the following standard

## **ISO 9001:2008**

Issued on: **2017 - 10 - 13**

First issued on: **2002 - 11 - 26**

for the validity date, please refer to the original certificate\* issued by IMQ

Registration Number: IT - 112265



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

### **IQNet Partners\*\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland  
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia  
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

\*\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



www.imq.it

**CERTIFICATO N.  
CERTIFICATE N. 9124.CRC4**

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

**CERACARTA SPA**

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

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

**EN ISO 13485:2012**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG.

Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

*Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione  
*Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization*

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

|              |                             |                           |                 |
|--------------|-----------------------------|---------------------------|-----------------|
| <b>DATE:</b> | <b>PRIMA CERTIFICAZIONE</b> | <b>EMISSIONE CORRENTE</b> | <b>SCADENZA</b> |
|              | <b>FIRST CERTIFICATION</b>  | <b>CURRENT ISSUE</b>      | <b>EXPIRY</b>   |
|              | 1999-07-20                  | 2017-10-13                | 2020-10-07      |

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28;  
in caso contrario, il presente certificato cesserà la propria validità in tale data  
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28;  
otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07  
Data di conclusione dell'audit di rinnovo: 2017-10-11  
Data della decisione di rinnovo: 2017-10-13

CISQ is a member of



*IQNet, the association of the world's first  
class certification bodies, is the largest  
provider of management System  
Certification in the world.*

*IQNet is composed of more than 30  
bodies and counts over 150 subsidiaries  
all over the globe.*



SGQ N°005A, SGA N°006D, SCR N°005F,  
SSI N°003G, FSM N°007I, SGE N°006M,  
EMAS N°003P, PRD N°005B, PRS N°008C,  
ISP N°003E, LAB N°012I, LAT N°002I

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

CISQ è la Federazione Italiana di  
Organismi di Certificazione dei  
sistemi di gestione aziendale.

*CISQ is the Italian Federation  
of management system  
Certification Bodies.*



www.cisq.com



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# DECLARATION OF CONFORMITY

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Forli, 18<sup>th</sup> January 2018

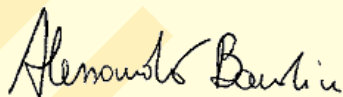
The devices named TOP TRACE & MEDISENSOR DISPOSABLE ELECTRODES FOR ECG (including models ST 50 RFI / RT 50 RFI & MEDISENSOR FS501-S) and the REUSABLE SUCTION CHEST AND CLAMP ELECTRODES have been produced by the company Ceracarta Spa on the basis of the essential requirements, see enclosure I of the directive 93/42/CEE, as prescribed in attachment VII of the above directive.

The writing company Ceracarta Spa located in Via Secondo Casadei n° 14, 47122 Forli, manufacturer of above listed DISPOSABLE & REUSABLE ELECTRODES declares under its own responsibility that such devices satisfy all the requirements of directive 93/42/CEE as amended by 2007/47/EC, about medical devices and in particular that:

- the Dispositives in object satisfy the essential requirements as in enclosure I of Directive 93/42/CEE;
- the Dispositives in object must be considered as belonging to Class I;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself;
- such documentation is available at the headquarters of Ceracarta, for any reference by the entitled bodies.

Sincerely,

CERACARTA SPA  
Bandini Alessandro

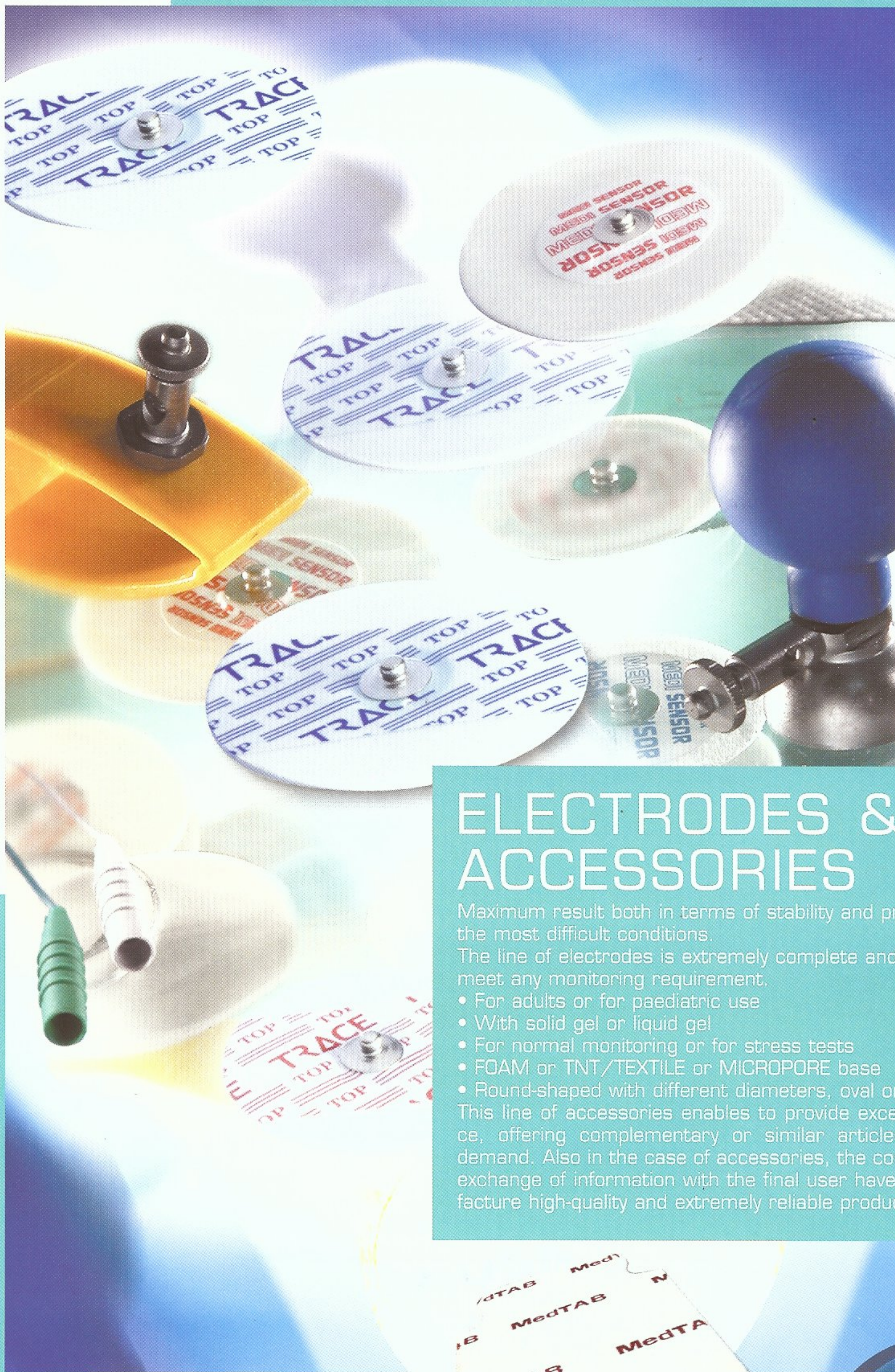


Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forli ITALY  
Tel: +39.0543780055 Fax: +39.0543781404  
<http://www.ceracarta.it> [info@ceracarta.it](mailto:info@ceracarta.it)



EN ISO 13485:2012





## 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

...for over  
**50**  
years  
CERACARTA  
Italy  
since...1960



## MONITORING &amp; RESTING ECG'S



NM 50 RFI

|         |                   |         |
|---------|-------------------|---------|
| Ø50 mm. | <b>Dimensions</b> | Ø55 mm. |
| Foam    | <b>Backing</b>    | Foam    |
| Solid   | <b>Gel</b>        | Liquid  |
| Ag/AgCl | <b>Sensor</b>     | Ag/AgCl |

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

**Packaging**

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

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



NM 55 RLI



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.



NM 3642 OFI



NP 30 RFI

|         |                   |           |
|---------|-------------------|-----------|
| Ø30 mm. | <b>Dimensions</b> | 28x44 mm. |
| Foam    | <b>Backing</b>    | Foam      |
| Solid   | <b>Gel</b>        | Solid     |
| Ag/AgCl | <b>Sensor</b>     | Ag/AgCl   |

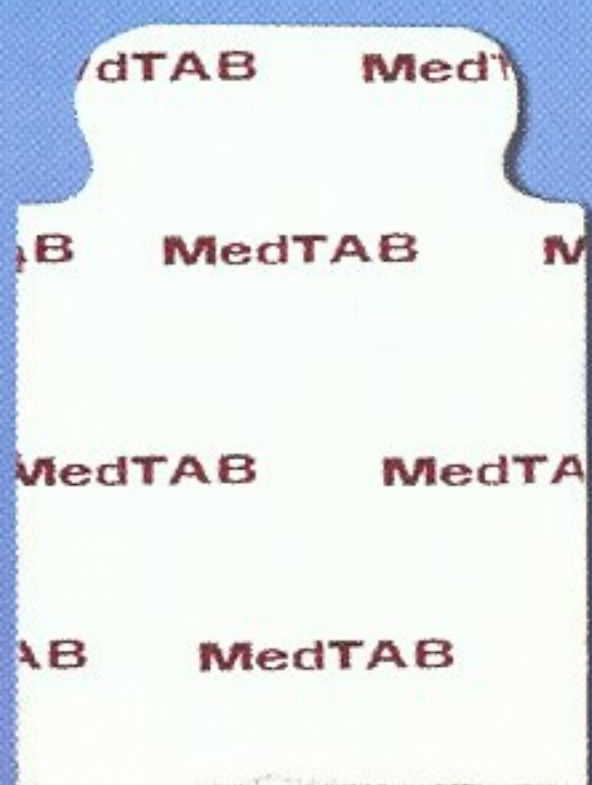
30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

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

NM 2844 RFS

**Packaging**

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



MEDTAB

|                             |                   |                       |
|-----------------------------|-------------------|-----------------------|
| 23x34 mm.                   | <b>Dimensions</b> | 28x44 mm.             |
| Silicone coated<br>pet film | <b>Backing</b>    | Foam                  |
| Solid                       | <b>Gel</b>        | Solid                 |
| Ag/AgCl                     | <b>Sensor</b>     | Ag/AgCl - Banana plug |

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.

NM 2844 FBI

**Packaging**

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



## STRESS TEST



### ST 50 RFI

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

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

#### Packaging

### ST 50 RLI



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

## HOLTER/LONG MONITORING



### NM 55 TNI

|          |                   |          |
|----------|-------------------|----------|
| Ø 55 mm. | <b>Dimensions</b> | Ø 50 mm. |
| TNT      | <b>Backing</b>    | Foam     |
| Solid    | <b>Gel</b>        | Solid    |
| Ag/AgCl  | <b>Sensor</b>     | Carbon   |

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

#### Packaging

## RADIO-TRANSPARENT



### RT 50 RFI

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

## MONITORING / PRE-WIRED ELECTRODES

### RE 30 LWF

30 mm.  
female 4 mm

|         |                   |         |
|---------|-------------------|---------|
|         | <b>Dimensions</b> |         |
| Foam    | <b>Backing</b>    | Foam    |
| Solid   | <b>Gel</b>        | Solid   |
| Ag/AgCl | <b>Sensor</b>     | Ag/AgCl |

3 pcs / pouch - 300 pcs / box

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

### RT 30 LWF

30 mm.  
female 4 mm

|        |                   |        |
|--------|-------------------|--------|
|        | <b>Dimensions</b> |        |
| Foam   | <b>Backing</b>    | Foam   |
| Solid  | <b>Gel</b>        | Solid  |
| Carbon | <b>Sensor</b>     | Carbon |

3 pcs / pouch - 300 pcs / box

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

### RE 22 LWS

22 mm.  
safety 1,55 mm

|         |                   |         |
|---------|-------------------|---------|
|         | <b>Dimensions</b> |         |
| Foam    | <b>Backing</b>    | Foam    |
| Solid   | <b>Gel</b>        | Solid   |
| Ag/AgCl | <b>Sensor</b>     | Ag/AgCl |

3 pcs / pouch - 300 pcs / box

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

### RT 22 LWS

22 mm.  
safety 1,55 mm

|        |                   |        |
|--------|-------------------|--------|
|        | <b>Dimensions</b> |        |
| Foam   | <b>Backing</b>    | Foam   |
| Solid  | <b>Gel</b>        | Solid  |
| Carbon | <b>Sensor</b>     | Carbon |

3 pcs / pouch - 300 pcs / box

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



# MEDI SENSOR LINE

## MONITORING & RESTING ECG'S

### MODEL F 50-S



Ø 50 mm.

Dimensions

Foam

Backing

Solid

Gel

Ag/AgCl

Sensor

30 pcs / pouch – 1200 pcs / carton

Available also with liquid gel Model F 50-L

### MODEL F 3642-S



Ø 42.5 x 36.5 mm.

Foam

Solid

Ag/AgCl

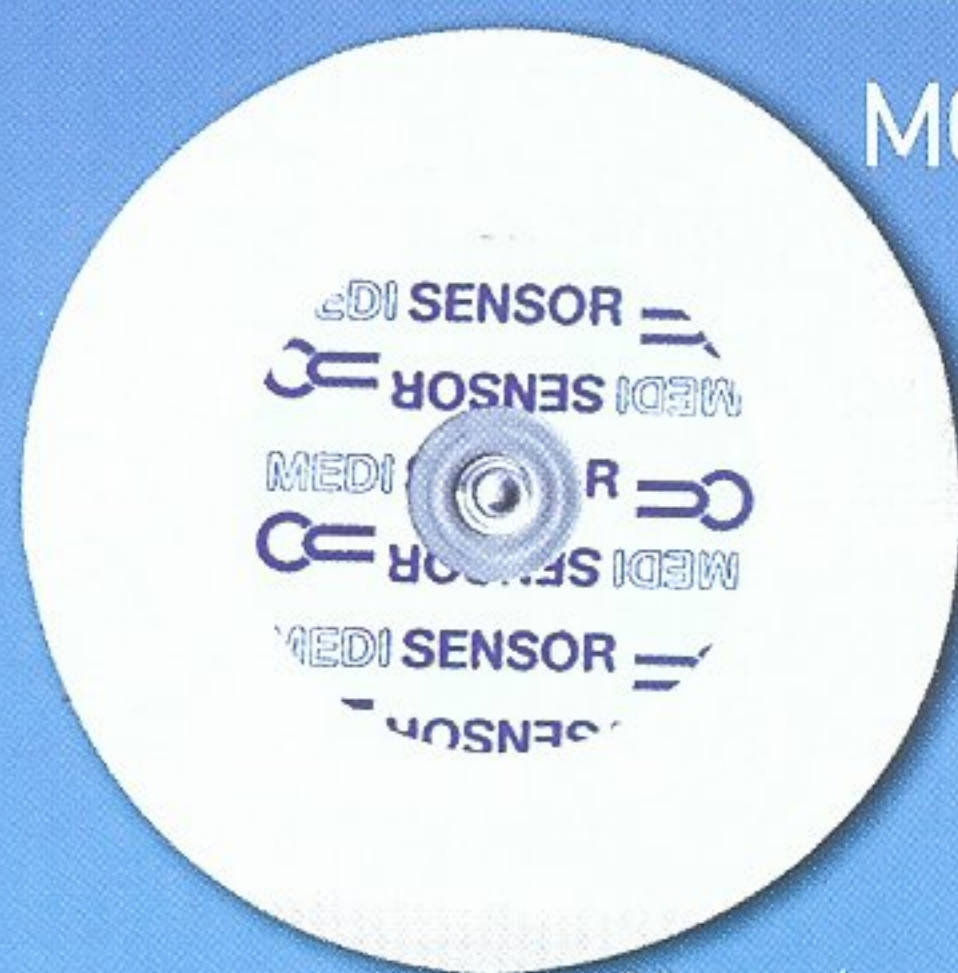
Packaging

50 pcs / pouch – 2000 pcs / carton

Available also with liquid gel Model F 3642-L

## HOLTER / LONG MONITORING

### MODEL W 601-S



Ø 55 mm.

Dimensions

TNT

Backing

Solid

Gel

Ag/AgCl

Sensor

30 pcs / pouch – 1500 pcs / carton

Available also with Ø 50 mm Model W 601  
and also with liquid gel Model W 601-L

### MODEL T 601-S



Ø 55 mm.

MICROPORE

Solid

Ag/AgCl

Packaging

30 pcs / pouch – 1500 pcs / carton

## STRESS TEST

### MODEL FS 50-L



Ø 50 mm.

Dimensions

Foam

Backing

Liquid

Gel

Ag/AgCl

Sensor

30 pcs / pouch – 1200 pcs / carton

Packaging

### MODEL F 55-L



Ø 55 mm.

Foam

Liquid

Ag/AgCl

30 pcs / pouch – 1200 pcs / carton

### MODEL FS 501-S



Ø 35x45 mm

Dimensions

Foam

Backing

Solid

Gel

Ag/AgCl

Sensor

50 pcs / pouch – 2000 pcs / carton

Packaging

### MODEL F 50-S BLUE

Ø 50 mm.

Foam

Solid

Carbon

30 pcs / pouch – 1200 pcs / carton

Ideal for all ECG monitoring, radiolucent application included!





## SUCTION CHEST ELECTRODES



Ag/AgCl sensor to guarantee maximum reliability in signal transmission • Suction cup made of a special /soft mixture to enhance the flexibility and therefore long duration over time.

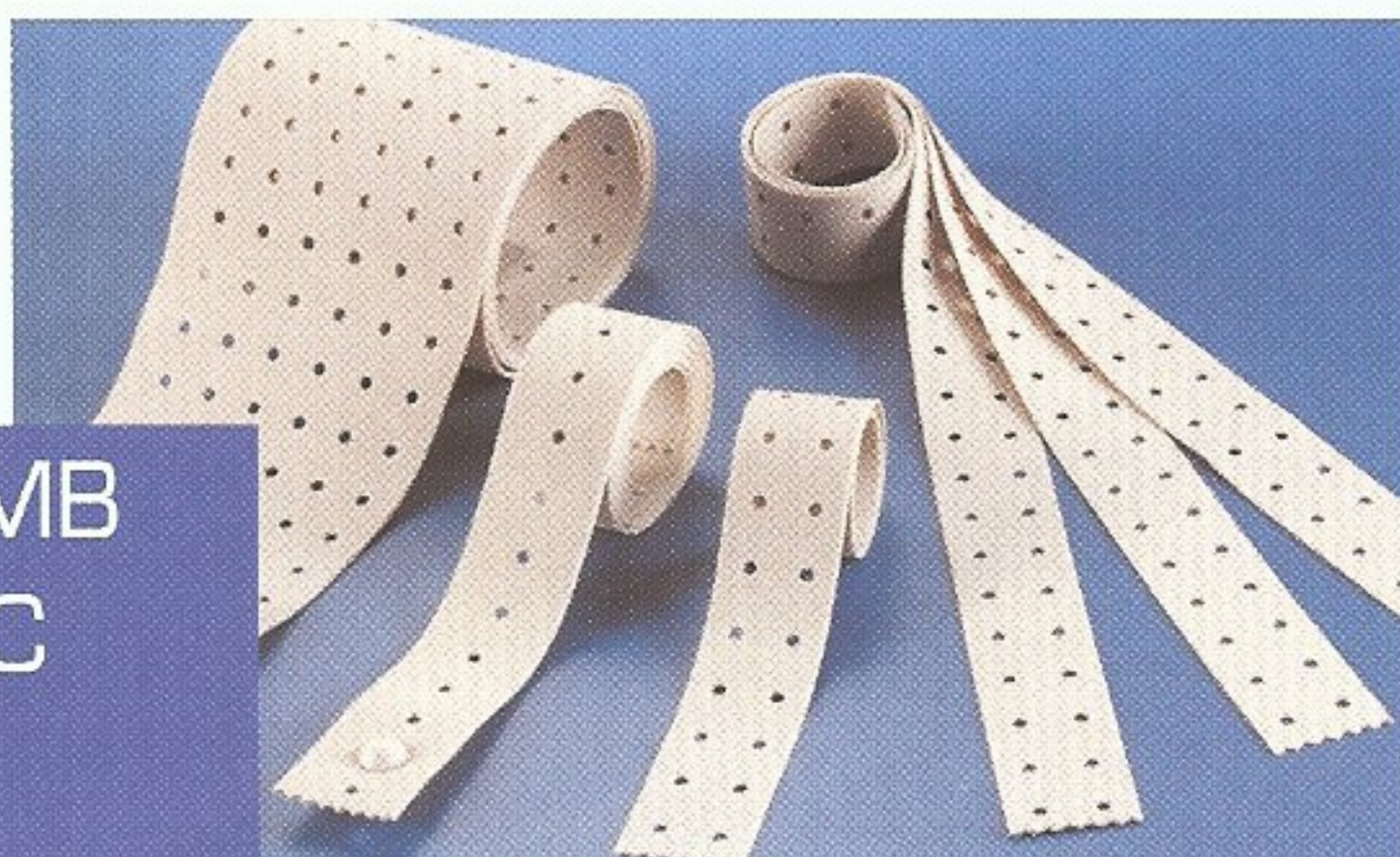
Available in three sizes: Ø15 mm for pediatric use / Ø 24 mm and Ø 30 mm for adult use.

## CLAMP ELECTRODES



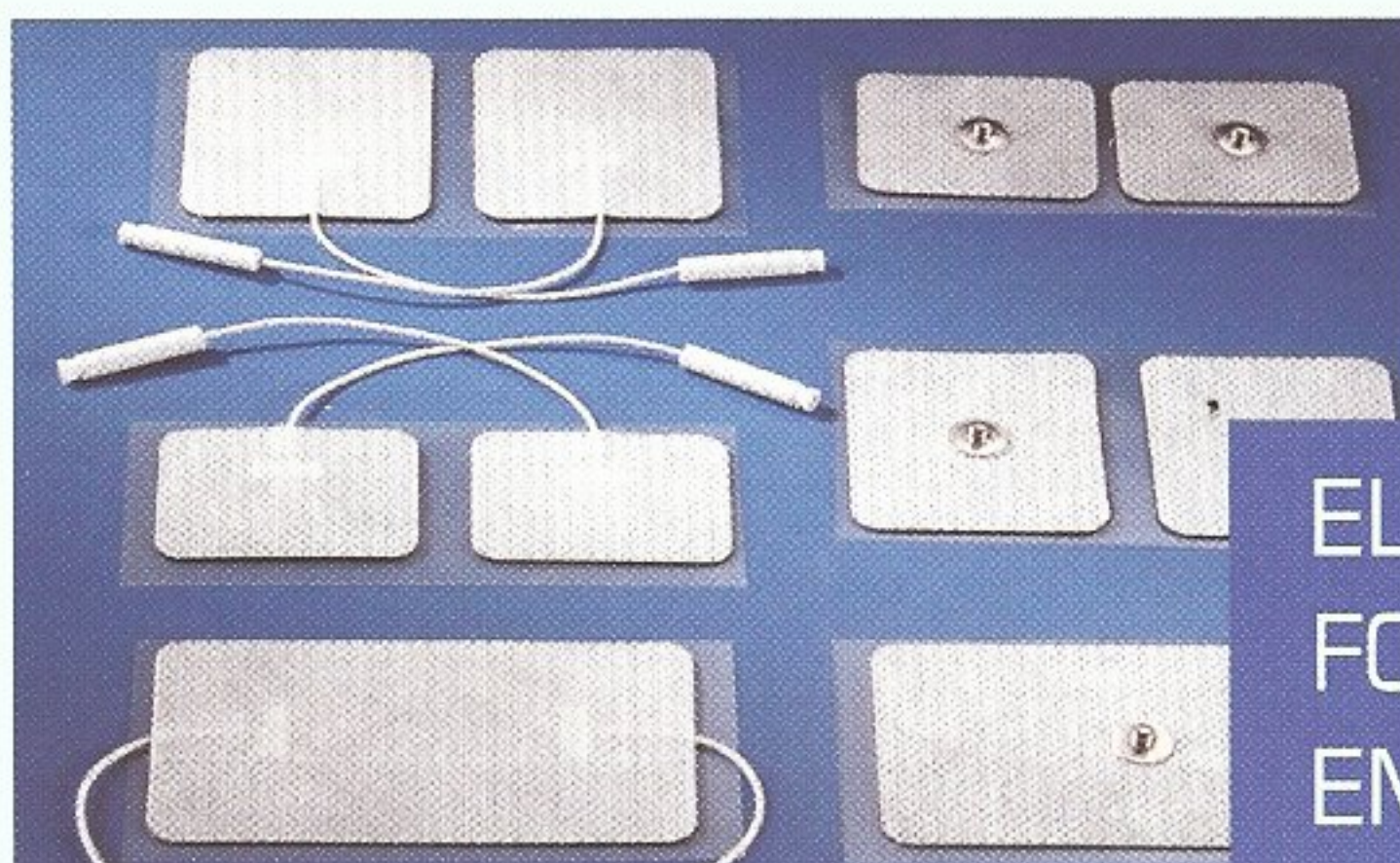
Classical-designed clamps with an improved quality. Ag/AgCl to ensure excellent signal transmission • Silver component to prevent distortions and to increase efficiency • Universal connection • Comply with AAMI standards • Available in yellow, green, red and black colours for adult and pediatric use.

## 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.

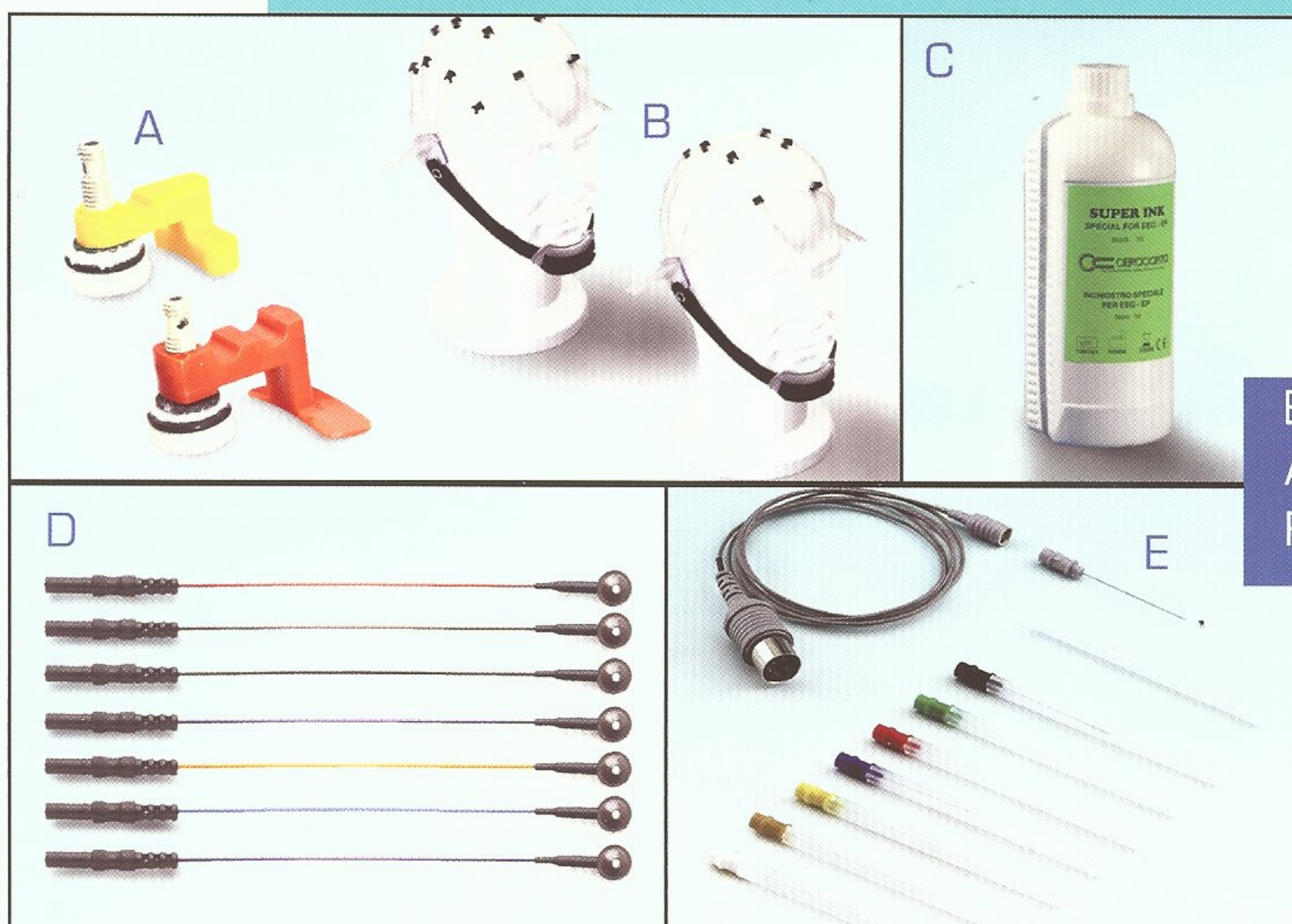
## PULSE OXIMETER SENSORS



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



## 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).

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• 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



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## DEFIBRILLATION PADS



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## 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.





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**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.

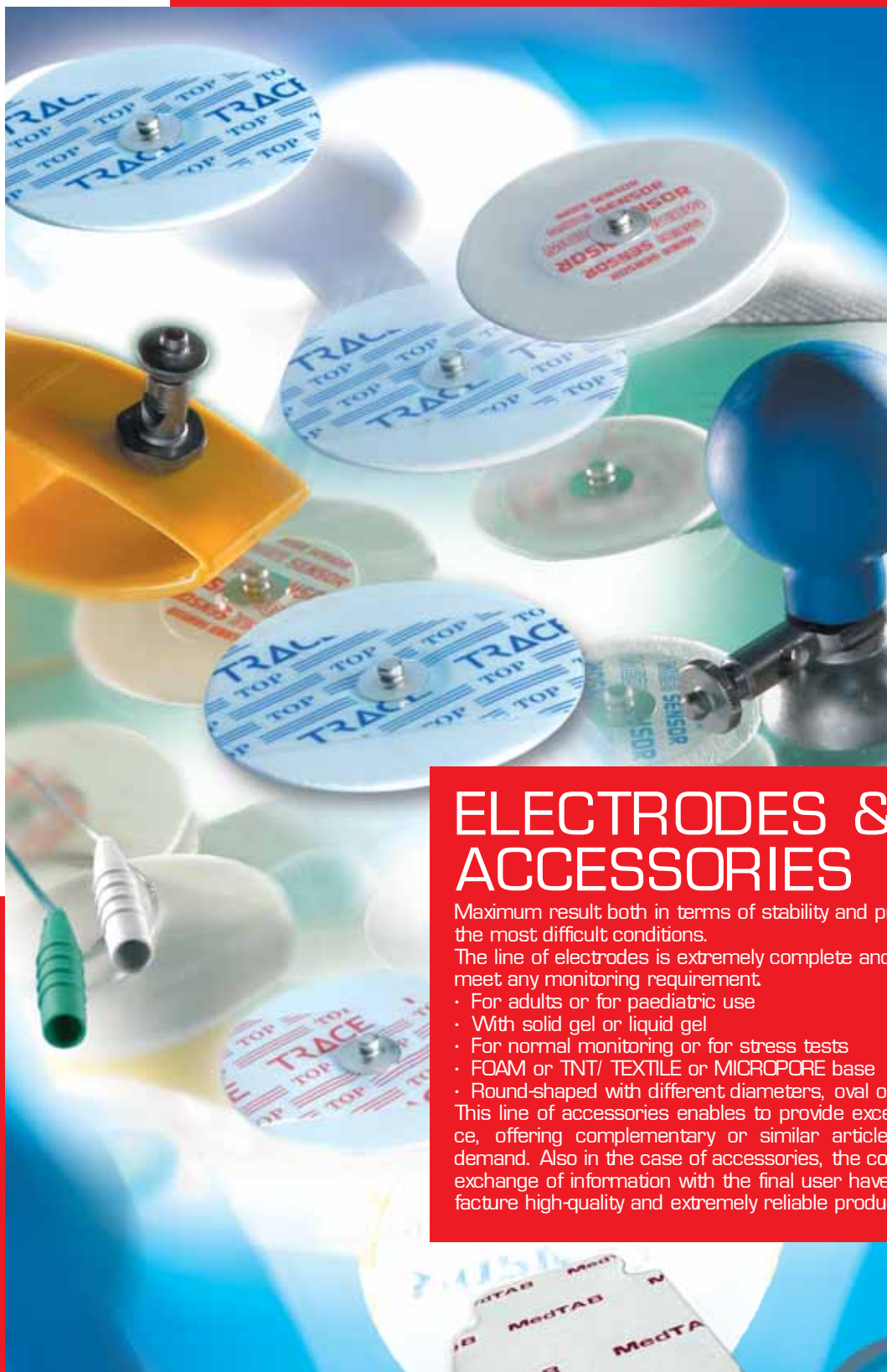


EC product compliance



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





## 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.<br>female 4 mm | <b>Dimensions</b> | 22 mm.<br>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> | Ø 50 mm. |
| Foam     | <b>Backing</b>    | Foam     |
| Solid    | <b>Gel</b>        | Liquid   |
| Ag/AgCl  | <b>Sensor</b>     | Ag/AgCl  |

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

### Packaging

## ST 50 RLI



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> | Ø 55 mm. |
| Foam     | <b>Backing</b>    | TNT      |
| Liquid   | <b>Gel</b>        | Solid    |
| Ag/AgCl  | <b>Sensor</b>     | Ag/AgCl  |

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

### Packaging

## NM 55 TNI



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.<br>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

**Backing** Foam

**Gel** Solid

**Sensor** 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.



Gessate, 7 February 2012

## CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC  
as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

### GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

### 93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

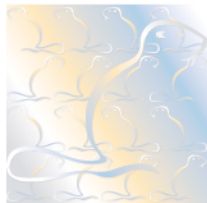
as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).
- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

**GIMA S.p.A.**  
Q.A. Department  
Nicola Manzoni







|                  |            |                  |            |
|------------------|------------|------------------|------------|
| Reg. Number      | 10164 - A  | Valid From       | 2021-10-14 |
| First issue date | 2012-10-15 | Last change date | 2021-10-14 |
| Valid Until      | 2024-10-14 | IAF Sector       | 29 a       |

## Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids.

Chief Operating Officer  
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

**Kiwa Cermet Italia S.p.A.**  
Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
**Kiwa Italia Holding Srl**  
Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)  
Tel +39.051.459.3.111  
Fax +39.051.763.382  
E-mail: [info@kiwacermet.it](mailto:info@kiwacermet.it)  
[www.kiwa.it](http://www.kiwa.it)

### **GIMA S.p.A.**

#### **Registered Headquarters**

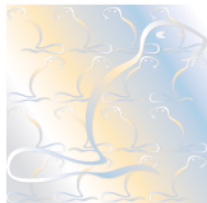
- Via Grossi, 2 20121 Milano - Italia

#### **Certified Sites**

- Via Marconi, 1 20060 Gessate (MI) - Italia







|                  |            |                  |            |
|------------------|------------|------------------|------------|
| Reg. Number      | 10164 - M  | Valid From       | 2021-10-14 |
| First issue date | 2012-10-15 | Last change date | 2021-10-14 |
| Valid until      | 2024-10-14 |                  |            |

## Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and production, packaging and service of:

General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).

Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

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Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
Kiwa Italia Holding Srl

Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)  
Tel +39.051.459.3.111  
Fax +39.051.763.382  
E-mail: [info@kiwacermet.it](mailto:info@kiwacermet.it)  
[www.kiwa.it](http://www.kiwa.it)

**CERMET**

**GIMA S.p.A.**

**Registered Headquarters**

- Via Grossi, 2 20121 Milano Italia

**Certified Sites**

- Via Marconi, 1 20060 Gessate (MI) - Italia







# GIMA

## BLADE ELECTRODE - 15 cm - autoclavable

**Code:** 30533

**Category:** Electrodes

**Unit of sale:** 1 pc.

**Minimum order:** 10

**Type:** Medical device

**Class:** II B

**NSIS:** 771101

**CND:** L9099

**EAN13:** 8033003261019

**Description:** Autoclavable electrodes Ø 2.4 mm  
Blade electrode  
Length: 15 cm  
Reference number: 36

**AUTOCLAVABLE 20 TIMES**







# GIMA

## MB AUTOCLAVABLE HANDLE 100 times - 3 m cable

|                       |                                         |
|-----------------------|-----------------------------------------|
| <b>Code:</b>          | <b>30554</b>                            |
| <b>Category:</b>      | <b>Monopolar electrosurgery handles</b> |
| <b>Unit of sale:</b>  | <b>1 pc.</b>                            |
| <b>Minimum order:</b> | <b>1</b>                                |
| <b>Type:</b>          | <b>Medical device</b>                   |
| <b>Class:</b>         | <b>II B</b>                             |
| <b>NSIS:</b>          | <b>1729229</b>                          |
| <b>CND:</b>           | <b>Z12010980</b>                        |
| <b>EAN13:</b>         | <b>8033695725684</b>                    |



**Description:** Autoclavable handle with 2 large "click" push-button, provided with a 3 meters long silicone cable and a blade electrode. It can be autoclaved up to 100 times (20 times electrode). For electrodes Ø 2.4 mm.

GIMA autoclavable electrosurgery pencils with CUT-COAG switch have been studied and tested to offer maximum reliability and functionality to the operator. MB handles are provided with a 3 Pins socket Valley Lab type that fits all Gima mono-bipolar Diatermo MB (122, 132, 160, 200, 202, 240, 380) and majority of bipolar electrosurgical units: Aspen Lab, ES Generator, EMC Statome, Danieli, Braun, Berchtold, Ohmeda, Ritter, Conmed, Eschman, Bovie, Martin, Kontron, Bard, Birtcher 771, Cobi, Valley Lab, Led, Erbe...





# GIMA

## ULTRASOUND GEL - tank 5 l - transparent

**Code:** 33277

**Category:** Ultrasound gel

**Unit of sale:** box of 2 pcs.

**Minimum order:** 1

**Type:** Medical device

**Class:** I

**NSIS:** 241683

**CND:** V9099

**EAN13:** 8023279332773



**Description:** Hypoallergenic, water soluble gel suitable for ultrasonography, doppler and defibrillator applications. It ensures the ultrasound waves come to the equipment display in a clear and uninterrupted way. Salt, formaldehyde, fragrance free.

- Includes 2 empty bottles 250 ml





# GIMA

## RESPIPROGRAM LUNG EXERCISER

**Code:** 33442

**Category:** Peak flow meters - asthma

**Unit of sale:** 1 pc.

**Minimum order:** 1

**Type:** Medical device

**Class:** I

**NSIS:** 586372

**CND:** Y030327

**EAN13:** 8023279334425



**Description:** Device to exercise the respiration through inspiration.

The respiratory-exerciser Respiprogram helps the patient to recover the normal respiration after a chest or abdominal surgery.

The device is composed of: 1 base, 3 small balls different in dimension and colours, 1 transparent central part divided into 3 rooms, 1 tube and mouthpiece.

Each unit packed in single box.

Made in Italy.

Multilanguage box and instruction: GB, FR, IT, ES, PT, DE, GR, Arab.





**AB UYGUNLUK BEYANI**  
**EC DECLARATION OF CONFORMITY**



**ÜRETİCİ FİRMA ADI:**  
**COMPANY NAME:**

Turkuaz Sağlık Hizmetleri Medikal Temizlik  
Kimyasal Ürünler Sanayi ve Ticaret A.Ş.  
Yakuplu Mahallesi, Birlik Caddesi, No: 32/1,  
34524, Beylikdüzü / İstanbul / Türkiye

**ADRES:**  
**ADDRESS:**

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**TELEPHONE:**

+902124286848

**FAKS:**  
**FAX:**

+902124286853

**E-MAIL:**

info@turkuazsaglik.com.tr

**Avrupa Yetkili Temsilcisi**  
**European Authorized**  
**Representative**

Obelis s.a  
Bd. Général Wahis 53  
1030 Brussels, BELGIUM

Tel: +(32) 2.732.59.54  
Fax: +(32) 2.732.60.03  
E-Mail :  
[mail@obelis.net](mailto:mail@obelis.net)

**ÜRÜN ADI:**  
**PRODUCTS:**

Ultrasonografi Jeli  
Non-Sterile Ultrasound Gel

**MARKA:**  
**TRADE MARK:**

Konix

**Modeller ve Referans No.:**  
**MODEL(S) and Ref No.:**

|                  |                |
|------------------|----------------|
| 20 ml            | T01.01.01.0134 |
| 60 ml            | T01.02.0039    |
| 250 ml           | T06.02.0007    |
| 500 ml           | T06.02.0111    |
| 1000 ml          | T06.02.0008    |
| 5000 ml          | T06.02.0009    |
| 5000 ml (Gallon) | T06.02.0145    |

**GMDN KODU:**

15321

**GMDN CODE:**

**SINIFLANDIRMA:**  
**CLASSIFICATION:**

Annex IX of The MDD 93/42 EEC Class I, Rule 1

**UYGUNLUK DEĞERLENDİRME YOLU:**  
**CONFORMITY ASSESSMENT ROUTE:**

MDD 93/42/EEC ANNEX 7

**UYGULANABİLİR STANDARTLAR:**  
**APPLICABLE STANDARDS:**

EK I'e bakınız  
See Appendix I

**VERİLİŞ TARİHİ:**  
**ISSUE DATE:**

6.06.18

**YUKARIDA ADI GEÇEN ÜRÜNLERİN 2007/47/EC EKLENTİSİ DAHİL 93/42/EEC TIBBİ CİHAZLAR YÖNETMELİĞİ GEREKSİNİMLERİNİ KARŞILADIĞINI BEYAN EDERİZ. İLGİLİ DESTEKLEYİCİ TÜM DOKÜMANLAR ÜRETİCİ TESİSİNDE BULUNMAKTADIR.**

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC INCLUDING 2007/47/EC AMENDMENT FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**İMZA:**  
**SIGNATURE:**

Nurhan IRMAK  
**GENEL MÜDÜR YARDIMCISI**  
**DEPUTY GENERAL MANAGER**

**TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL**  
**TEMİZLİK KİMYASAL ÜRÜNLER SAN VE TİC. A.Ş.**  
Yakuplu Mah. Birlik Cad. No:32/1 İç Kapı No: 3  
Beylikdüzü / İSTANBUL  
Tel: +90 212 428 68 48 Fax: +90 212 428 68 53  
Yenikapı / İstanbul 34524  
Tic. Sic. No: 2750836

**Bölüm No. Chapter No.:** TD-xx/1.2  
**Rev. Tarihi Rev. Date:** 06.06.2018

**Yayın Tarihi Release Date:** 03.07.2017  
**Rev. No.:** 4

Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret A.Ş.

Yakuplu Mah. Birlik Cad. No: 32/1 (Beysan Sanayi Sitesi) 34524 Beylikdüzü - İstanbul - Türkiye  
T. +90 212 428 68 48 F. +90 212 428 68 53 [www.turkuazsaglik.com.tr](http://www.turkuazsaglik.com.tr)



koniCARE



KLY.



## Silicone tubing. Non toxic

For use in a variety of medical, pharmaceutical, industrial and clinical applications. Translucent tubing. Very high mechanical and chemical resistance. Silicone tubing has a chemical composition similar to quartz and glass and share their excellent properties.

**Autoclavable.** Made with materials suitable for alimentary use.

### Technical features:

Specific gravity: 1.2 + 0.1. Toughness: 40 - 80 Sh.

Resistance to traction: 77-95 kg/cm<sup>2</sup>. Extension: 275-780%

Resistance to tearing: 20-50 kg/cm<sup>2</sup>. Temperature range: **-50 °C to 200 °C** (beaks of **250 °C**). Pressure range: up to 1.5 bar

| code   | dimensions mm<br>Ø int. x Ø ext. | bag quantity<br>(meters) | bag weight | bag volume |
|--------|----------------------------------|--------------------------|------------|------------|
| 350051 | 0.5 x 1                          | 1 x 100                  | 0.08       | 0.0011     |
| 350013 | 1 x 3                            | 1 x 15                   | 0.12       | 0.0010     |
| 350024 | 2 x 4                            | 1 x 15                   | 0.23       | 0.0016     |
| 350034 | 3 x 4                            | 1 x 15                   | 0.22       | 0.0043     |
| 350035 | 3 x 5                            | 1 x 15                   | 0.26       | 0.0026     |
| 350037 | 3 x 7                            | 1 x 15                   | 0.51       | 0.0032     |
| 350046 | 4 x 6                            | 1 x 15                   | 0.56       | 0.0026     |
| 350048 | 4 x 8                            | 1 x 15                   | 0.80       | 0.0043     |
| 350057 | 5 x 7                            | 1 x 15                   | 0.38       | 0.0039     |
| 350059 | 5 x 9                            | 1 x 15                   | 0.83       | 0.0047     |
| 350069 | 6 x 9                            | 1 x 15                   | 0.61       | 0.0100     |
| 350610 | 6 x 10                           | 1 x 15                   | 0.83       | 0.0096     |
| 350612 | 6 x 12                           | 1 x 15                   | 0.22       | 0.0043     |
| 350079 | 7 x 9                            | 1 x 15                   | 0.63       | 0.0091     |
| 350710 | 7 x 10                           | 1 x 15                   | 0.70       | 0.0076     |
| 350810 | 8 x 10                           | 1 x 15                   | 0.67       | 0.0091     |
| 350812 | 8 x 12                           | 1 x 15                   | 1.11       | 0.0054     |
| 350814 | 8 x 14                           | 1 x 15                   | 1.87       | 0.0008     |
| 350912 | 9 x 12                           | 1 x 15                   | 0.82       | 0.0120     |
| 350915 | 9 x 15                           | 1 x 15                   | 0.22       | 0.0043     |
| 351014 | 10 x 14                          | 1 x 15                   | 1.43       | 0.0081     |
| 351420 | 14 x 20                          | 1 x 15                   | 2.72       | 0.0240     |
| 351622 | 16 x 22                          | 1 x 15                   | 4.15       | 0.0320     |
| 352030 | 20 x 30                          | 1 x 15                   | 7.00       | 0.0490     |

NOTE: Tube thickness =  $\frac{\text{external } \varnothing - \text{internal } \varnothing}{2}$



## Silicone sheets

50 x 50 cm silicone sheets ideal as a laboratory benchtop protection or for use in autoclaves to protect any material.

For cleaning simply use a wet cloth.

**Resistant up to 230 °C.**



| code   | thickness mm | bag quantity | bag weight | bag volume |
|--------|--------------|--------------|------------|------------|
| 350002 | 2            | 1            | 0.60       | 0.030      |
| 350004 | 4            | 1            | 1.20       | 0.001      |





S/REF  
N/REF: PS/DP/MST  
Date: 01/12/2015  
Subject: Information to the addressee

DELTALAB, S.L.  
PLAZA DE LA VERNEDA, 1  
POLIGONO INDUSTRIAL LA LLANA  
081191 RUBÍ  
(BARCELONA)

In response to your email dated 24/11/2015 requesting information on the products detailed below, which are included as items for general laboratory use in your company's catalogue, and after having made the relevant inquiries, I can inform you that:

- Slides
- Uncoated cover slides
- Pasteur pipettes
- Tips for general purpose pipettes
- Sample cups and cuvettes
- Spreaders for extensions
- Calibrated loops
- Petri dishes
- Vials
- Caps
- Serological pipettes
- Cryovials
- Ritips
- Cassettes for biopsy
- Microtitre plates
- E.S.R. system stands
- Anticoagulants and preservatives in bulk
- Stains for microbiology.

[State seal]  
MINISTRY OF HEALTH, SOCIAL  
SERVICES AND EQUALITY  
SUPPORTING RECORD  
AGENCIA ESPAÑOLA DE  
MEDICAMENTOS Y PRODUCTOS  
SANITARIOS  
[SPANISH STATE AGENCY OF MEDICATION  
AND SANITARY PRODUCTS]  
EXIT  
Registration No: 26082/RG53761  
Date: 14/12/2015 09:24:32

These products do not fall under the scope of Royal Decrees 1591/2009 of 16 October and 1662/2000 of 29 September, which regulate medical devices and medical devices for in vitro diagnostics respectively. These decrees transpose Directive 93/42/EEC on medical devices and Directive 98/79/EC of the European Parliament and of the Council dated 27 October 1998 on in vitro diagnostic medical devices to Spanish legislation, therefore their marketing falls under commercial legislation, consumer and user protection legislation and any applicable specific legislation.

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

[Illegible signature]  
M<sup>a</sup> del Carmen Abad Luna  
[Seal: Spanish State Agency of  
Medication and Sanitary Products]  
Page 1/1

C/CAMPEZO, 1-EDIFICIO 8  
28022 MADRID  
TELEPHONE: 91 822 52 61  
FAX: 91 822 52 89

Dña Marta Casanova Hernández, Traductora e  
Intérprete jurada de inglés nombrada por el Ministerio  
de Asuntos Exteriores y Cooperación certifica que la  
que antecede es traducción fiel y completa al inglés de  
un documento redactado en español.  
En Salamanca, a 15 de diciembre de 2015

I, Marta Casanova, Sworn Translator and Interpreter of  
English named by the Ministry of Foreign Affairs and  
Cooperation, hereby certify that the foregoing is a true  
and complete translation into English of a document  
written in Spanish.  
In Madrid, 15 December 2015

MARTA CASANOVA HERNANDEZ  
Traductora-Intérprete Jurada de INGLÉS

Marta Casanova

## Declaración de Conformidad "CE" "CE" Declaration of conformity

Directiva Productos Sanitarios para el Diagnóstico In Vitro 98/79/CE  
In Vitro Diagnostic Medical Devices Directive 98/79/EC

Fabricante / Manufacturer: **AQUISEL, s.l.**  
Dirección / Address: Autovía A-2 Km 585,1 08630 ABRERA (BARCELONA) - SPAIN

Declaro bajo su responsabilidad que los productos listados debajo, han estado diseñados para la aplicación de diagnóstico In Vitro y cumplen todos los requisitos esenciales del anexo I del Real Decreto 1662/2000 transposición a la Legislación Española de la Directiva 98/79/CE sobre productos sanitarios para diagnóstico In Vitro.

Declares under their responsibility that the products listed below have been designed for In Vitro diagnostic application and that they comply with all essential requirements as laid out in Annex I of Real Decreto 1662/2000 transposition to the Spanish Legislation of the Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

"Tubos AQUISEL"; contenedores para la recogida de muestras de sangre, variantes:  
The "AQUISEL tube"; containers for blood sampling collection, kinds:

- |                                                                          |                                                                   |
|--------------------------------------------------------------------------|-------------------------------------------------------------------|
| • K3E/EDTA 3K (anticoagulante)                                           | • K3E/EDTA 3K (anticoagulant)                                     |
| • K2E/EDTA 2K (anticoagulante)                                           | • K2E/EDTA 2K (anticoagulant)                                     |
| • 4NC/CITRATO 3Na (anticoagulante)                                       | • 4NC/Citrate 3Na (anticoagulant)                                 |
| • 9NC/CITRATO 3Na (anticoagulante)                                       | • 9NC/Citrate 3Na (anticoagulant)                                 |
| • LH/Heparina LI (anticoagulante)                                        | • LH/LI Heparin (anticoagulant)                                   |
| • LH/LI Heparina LI - Gel (anticoagulante)                               | • LH/LI Heparin + Gel (anticoagulant)                             |
| • MonoiodoAcetato LI + Gránulos PS activador (antiglicolítico)           | • IodoAcetate LI + Granules activator (antiglycolitic)            |
| • LH/Heparina LI + MonoiodoAcetato LI (anticoagulante + antiglicolítico) | • LH/LI Heparin + IodoAcetate LI (anticoagulant + antiglycolitic) |
| • FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante)          | • FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant)     |
| • Z/Vacio (sin aditivos)                                                 | • Z/Empty (non additive)                                          |
| • Z/ Tubo tratado (para suero)                                           | • Z/ Treatment Tube (for serum)                                   |
| • Z/ Tubo tratado con Gel separador (para suero)                         | • Z/ Treatment Tube with Separator Gel (for serum)                |
| • Z/ Tubo tratado con Gránulos PS (para suero)                           | • Z/ Treatment Tube with Granules PS (for serum)                  |
| • Z/ Tubo con activador de la coagulación (para suero)                   | • Z/ Tube with clotting activator (for serum)                     |
| • Z/ Tubo con activador + Gel separador (para suero)                     | • Z/ Tube with clotting activator + Separator Gel (for serum)     |
| • Z/ Tubo con activador + Gránulos PS (para suero)                       | • Z/ Tube with clotting activator + Granules PS (for serum)       |

Accesorios  
• CAP-GALET (Embudo para muestras de sangre)

Accesorios  
• CAP-GALET (Funnels for Blood Sampling)

Abre a 09 Octubre de 2014 , Abre a 09th October 2014

Firmado/Signed:   
(Gerente / Manager)

AQUISEL, S.L. 08630 ABRERA ( Barcelona ) España Tl: (93) 770 39 00 Fax: (93) 770 39 15



## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

DELTALAB S.L.  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBÍ (BARCELONA) - SPAIN

Declaro bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL DE TOMA DE MUESTRAS CON Y SIN MEDIO DE  
TRANSPORTE MARCA EUROTUBO  
INVASIVE STERILE EUROTUBO COLLECTION SWAB FOR SAMPLE COLLECTION WITH  
AND WITHOUT TRANSPORT MEDIUM  
(Códigos según Anexo 1 / Codes in Annex 1)

Tipo: Sistema invasivo estéril de recogida de muestras por contacto directo con el paciente  
Type: Invasive sterile collection system by direct contact with the patient

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis  
microbiológicos  
Intended Use: Collection and transport of biological samples for subsequent microbiological  
analysis

Código GMDN / GMDN Code: 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

### ESCOBILLON - Swab

Directiva 93/42/CEE Directiva Productos Sanitarios.  
Transposición a la legislación española en Real Decreto 1591/2009.  
Directive 93/42/ECC Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1591/2009.

Clasificación: Clase IIa  
Classification: Class IIa

### INFORMACIÓN ADICIONAL

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0474 CP  
Epigrafe 1, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE,  
emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número  
0318.

### OTHER INFORMATION:

Regarding the swabs, this documentation is supported by the CE Certificate number 2005.06.0474 CP Epigraph 1,  
Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española  
de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.



## TUBO CON MEDIO DE TRANSPORTE - Tube with transport medium

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.  
Transposición a la legislación española en Real Decreto 1662/2000.  
Directive 98/79/EC In vitro Diagnostic Medical Devices Directive,  
Transposition to Spanish legislation in Real Decreto 1662/2000.

  
José Saez  
Director General / Managing Director

  
Anna Mir  
Responsable Técnico / Technical Director



**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS**  
**ANNEX 1 – ARTICLES DESCRIPTION**

| REF    | DESCRIPCIÓN                        | DESCRIPTION                    |
|--------|------------------------------------|--------------------------------|
| 300200 | ESCOBILLON MAD.+ALGODON PEEL/1     | SWAB I/W PEEL/1 WOOD+COTTON    |
| 300201 | ESCOBILLON PS+ALGODON PEEL/1       | SWAB I/W PEEL/1 PS+COTTON      |
| 300202 | ESCOBILLON PS+VISCOSA PEEL/1       | SWAB I/W PEEL/1 PS+VISCOS      |
| 300203 | ESCOBILLON ALU+ALGODON PEEL        | SWAB I/W PEEL ALUM+COTTON      |
| 300210 | ESCOBILLON MAD.+ALGOD. B/2 PEEL    | SWAB B/2 PEEL/2 WOOD+COTTON    |
| 300250 | ESCOBILLON MAD.+ALGODON TUBO       | SWAB IN TUBE WOOD+COTTON       |
| 300251 | ESCOBILLON ALU.+ALGODON TUBO       | SWAB IN TUBE ALUM+COTTON       |
| 300252 | ESCOBILLON PS+VISCOSA TUBO         | SWAB IN TUBE PS+VISCOS         |
| 300253 | ESCOBILLON ALU.+VISCOSA TUBO       | SWAB IN TUBE ALUM+VISCOS       |
| 300254 | ESC. ALUM. TRENZADO+VISCOSA TUBO   | SWAB TWISTED ALUM+VISCOS       |
| 300259 | ESCOBILLON MAD.+VISCOSA TUBO       | SWAB IN TUBE WOOD+VISCOS       |
| 300261 | ESCOBILLON PS+ALGODON TUBO         | SWAB IN TUBE PP+COTTON         |
| 300263 | ESCOBILLON 13X165MM PS C/POLIESTER | SWAB 13X165MM PS W/POLYESTER   |
| 300280 | CARY BLAIR MADERA+ALGODON          | CARY BLAIR SWAB WOOD+COTTON    |
| 300281 | AMIES ALUMINIO+VISCOSA             | AMIES SWAB ALUMINIUM+VISCOS    |
| 300284 | AMIES LIQUIDO PS+VISCOSA           | AMIES SWAB LIQUID PS+VISCOS    |
| 300285 | AMIES CARBON PS+VISCOSA            | AMIES+CHARCOAL SWAB PS+VISCOS  |
| 300287 | AMIES PS+VISCOSA                   | AMIES SWAB PS+VISCOS           |
| 300290 | STUART MADERA+ALGODON              | STUART SWAB WOOD+COTTON        |
| 300291 | STUART ALUMINIO+ALGODON            | STUART SWAB ALUM+COTTON        |
| 300292 | STUART ALUMIN. TRENZADO+VISCOSA    | STUART SWAB TWISTED ALU + VISC |
| 300294 | VIRUS ALUMINIO + POLIESTER         | VIRUS SWAB ALUMINIUM POLYESTER |
| 300295 | STUART 13X165MM PS C/VISCOSA       | STUART 13X165MM PS W/VISCOS    |
| 300296 | H. VIRUS ALUM. ALGODON             | SWAB FOR VIRUS WIRE+COTTON TIP |
| 300297 | VIRUS PS+POLIESTER                 | VIRUS SWAB PS POLYESTER        |
| 300299 | CHLAMYDIA PS+POLIESTER             | CHLAMYDIA SWAB PS+POLYESTER    |
| 310200 | ESCOBILLON MAD.+ALGODON FLOW       | WOOD+COTTON SWAB FLOW          |
| 310202 | ESCOBILLON PS+VISCOSA FLOW         | PS+VISCOS SWAB FLOW            |

Fecha / Date: 20/05/2016  
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| REF       | DESCRIPCIÓN                       | DESCRIPTION                     |
|-----------|-----------------------------------|---------------------------------|
| 300211.1  | ESCOBILLON PS+ALG. PACK PEEL/2    | SWAB B/2 PS+COTTON PEEL/2       |
| 300212.1  | ESCOBILLON PS+VISCOSA PEEL/2      | SWAB PEEL/2 PS+VISCOS           |
| 300250.1  | ESCOBILLON MAD.+ALGOD. PURO TU    | SWAB IN TUBE WOOD+PURE COTTON   |
| 300250.M  | ESCOBILLON MAD.+ALGODON TUBO      | SWAB IN TUBE WOOD+COTTON        |
| 300261.M  | ESCOBILLON PS+ALGODON TUBO        | SWAB IN TUBE PS+COTTON          |
| 300268.B  | ESCOBILLON PS+POLIESTER PEEL PACK | SWAB PS+POLIESTER IND.WRAPPED   |
| 300280.2  | CARY BLAIR PS+VISCOSA             | CARY BLAIR SWAB PS+VISCOS       |
| 300281/1  | ESC. AMIES+CARBON ALUM.VISCOSA    | AMIES CHARCOAL SWAB WIRE+VISCOS |
| 300281T   | AMIES ALUMINIO TRENZADO+ VISCOS   | AMIES SWAB TWIST.WIRE+VISCOS    |
| 300281TC  | AMIES+CARBON ALU.TRENZADO+ VISC   | AMIES+CHARCOAL TWIS.WIRE+VISCOS |
| 300285.M  | AMIES CARBON PS VISCOSA 6x100     | AMIES CHARCOAL PS RAYON 6X100   |
| 300287.5  | AMIES PS VISCOSA CAJAS 6x100      | AMIES PS VISCOS CASES 6X100     |
| 300287.A  | ESCOB.AMIES PS+VISCOSA            | AMIES SWAB PS+VISCOS            |
| 300295C   | STUART CARBÓN PS + VISCOSA        | STUART+CHARCOAL SWAB PS+VISCOS  |
| 310253.1  | ESCOB. ALUM+VISCOSA FLOW          | ALUM+VISCOS SWAB FLOW           |
| 310211.1  | ESCOBILLON PS+ALGODON B/2 FLOW    | PS+COTTON SWAB B/2 FLOW         |
| 300250.MY | ESCOBILLON MAD.+ALGODON TUBO      | SWAB IN TUBE WOOD+COTTON        |
| 300211.10 | ESCOBILLON PS+ALG. PACK PEEL/10   | SWAB PS+COTTON PEEL/10          |
| 300261AV  | ESCOBILLON PS+ALGODON TUBO        | SWAB IN TUBE PS+COTTON          |

Fecha / Date: 20/05/2016  
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CDCE-54 Rev.14

**DECLARACIÓN DE CONFORMIDAD CE**  
**CE DECLARATION OF CONFORMITY**

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, nº 1  
Pol. Ind. La Liana  
08191 Rubí (Barcelona) – España

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**SISTEMA INVASIVO ESTÉRIL, CON PUNTA ABSORBENTE, PARA TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE.**  
**INVASIVE STERILE COLLECTION SWAB, WITH ABSORBENT TIPPED, FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Tipo:** Escobillón estéril con punta absorbente para la recogida de muestras.  
**Type:** Absorbent tipped sterile swab for samples collection.

**Finalidad Prevista:** Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos  
**Intended Use:** Collection and transport of biological samples for subsequent microbiological analysis

**Código GMDN / GMDN Code:** 33722

**CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:**  
**CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:**

**ESCOBILLON - Swab**

**Directiva 93/42/CEE** Directiva Productos Sanitarios.  
Transposición a la legislación española en **Real Decreto 1591/2009.**  
**Directive 93/42/EEC** Medical Devices Directive.  
Transposition to Spanish legislation in **Real Decreto 1591/2009.**

**Clasificación:** Clase I Estéril  
**Classification:** Class I Sterile

**INFORMACIÓN ADICIONAL**

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0475 CP Epígrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

**OTHER INFORMATION:**

For the swabs, this documentation is supported by the CE Certificate number 2005.06.0475 CP Epigraph 6, according to Annexes VII section 5 and V section 3 of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

Fecha / Date: 20/05/2016  
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CDCE-86 Rev.4

**TUBO CON MEDIO DE TRANSPORTE – Tube with transport medium**

**Directiva 98/79/CE** Directiva Productos Sanitarios para Diagnóstico In Vitro.  
Transposición a la legislación española en **Real Decreto 1662/2000.**  
**Directive 98/79/EC** In vitro Diagnostic Medical Devices Directive.  
Transposition to Spanish legislation in **Real Decreto 1662/2000.**

José Saez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director

DELTALAB S.L.  
Plaza de la Verneda 1, Pol. Ind. La Liana  
08191 Rubí - Barcelona  
T. +34 936 995 000

Fecha / Date: 20/05/2016  
Pag. 2/4

CDCE-86 Rev.4



**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS/ANNEX 1 – ARTICLES DESCRIPTION**

| REF    | DESCRIPCIÓN                              | DESCRIPTION                                 |
|--------|------------------------------------------|---------------------------------------------|
| 300265 | ESCOBILLON PS+FLOCK EN TUBO              | SWAB / TUBE PS + FLOCK                      |
| 303806 | ESCOB.FLOCK ULTRA PEEL P.                | FLOCKED SWAB PS STAND.NO/BP ST.PEEL P.      |
| 304270 | VICUM 2ML ESC.FLOCK NASOFAR. 100MM       | VICUM 2ML FLOCKED SWAB NASOPH.100MM         |
| 304271 | VICUM 1ML ESC.FLOCK ESTANDAR 80MM        | VICUM 1ML FLOCKED SWAB STANDARD 80MM        |
| 304272 | VICUM 1ML ESC.FLOCK URETRAL 80MM         | VICUM 1ML FLOCKED SWAB URETRAL 80MM         |
| 304273 | VICUM 3ML ESC.FLOCK ESTANDAR 100MM       | VICUM 3ML FLOCKED SWAB STANDARD 100MM       |
| 304274 | VICUM 3ML ESC.FLOCK URETRAL 100MM        | VICUM 3ML FLOCKED SWAB URETRAL 100MM        |
| 304275 | VICUM 3ML ESC.FLOCK NASOFARINGEO 100MM   | VICUM 3ML FLOCKED SWAB NASOPH.100MM         |
| 304276 | VICUM 2ML ESC.FLOCK URETRAL 100MM        | VICUM 2ML FLOCKED SWAB URETRAL 100MM        |
| 304277 | VICUM 1ML ESC.FLOCK NASOFARINGEO 100MM   | VICUM 1ML FLOCKED SWAB NASOPH.100MM         |
| 304278 | VICUM 2ML ESC.FLOCK ESTANDAR 80MM        | VICUM 2ML FLOCKED SWAB STANDARD 80MM        |
| 304279 | VICUM 2ML ESC.FLOCK MINITIP 100MM        | VICUM 2ML FLOCKED SWAB MINITIP 100MM        |
| 304280 | CARY BLAIR 2ML ESC.FLOCK ESTANDAR 80MM   | CARY BLAIR 2ML FLOCKED SWAB STANDARD 80MM   |
| 304281 | AMIES 1ML ESC.FLOCK ESTANDAR 80MM        | AMIES 1ML FLOCKED SWAB STANDARD 80MM        |
| 304282 | AMIES 1ML ESC.FLOCK URETRAL 80MM         | AMIES 1ML FLOCKED SWAB URETRAL 80MM         |
| 304285 | AMIES 1ML ESC.FLOCK NASOFARINGEO 100MM   | AMIES 1ML FLOCKED SWAB NASOPH. 100MM        |
| 304286 | AMIES 1ML ESC.FLOCK MINITIP 100MM        | AMIES 1ML FLOCKED SWAB MINITIP 100MM        |
| 304287 | AMIES 2ML ESC.FLOCK ESTANDAR 80MM        | AMIES 2ML FLOCKED SWAB STANDARD 80MM        |
| 304291 | VIRUS 1ML ESC.FLOCK ESTANDAR 80MM        | VIRUS 1ML FLOCKED SWAB STAND. 80MM          |
| 304292 | VIRUS 1ML ESC.FLOCK URETRAL 80MM         | VIRUS 1ML FLOCKED SWAB URETRAL 80MM         |
| 304293 | VIRUS 3ML ESC.FLOCK ESTANDAR 100MM       | VIRUS 3ML FLOCKED SWAB STANDARD 100MM       |
| 304294 | VIRUS 3ML ESC.FLOCK URETRAL 100MM        | VIRUS 3ML FLOCKED SWAB URETRAL 100MM        |
| 304295 | VIRUS 3ML ESC.FLOCK NASOFARINGEO 100MM   | VIRUS 3ML FLOCK SWAB NASOPH.100MM           |
| 304297 | VIRUS 1ML ESC.FLOCK NASOFARINGEO 100MM   | VIRUS 1ML FLOCK SWAB NASOPH.100MM           |
| 304296 | VIRUS 2ML ESC.FLOCK NASOFARINGEO 2X100MM | VIRUS 2ML FLOCK SWAB NASOPH. 100MM          |
| 304298 | VIRUS 2ML ESC.FLOCK NASOF + ST. 100/80MM | VIRUS 2ML FLOCK SWAB NASOPH. + ST. 100/80MM |

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| REF    | DESCRIPCIÓN                           | DESCRIPTION                              |
|--------|---------------------------------------|------------------------------------------|
| 304288 | AMIES 1ML 3 ESC.FLOCK MRSA            | AMIES 1ML 3 FLOCKED SWABS MRSA           |
| 304212 | LIM BROTH 2ML ESC.FLOCK ESTANDAR 80MM | LIM BROTH 2ML FLOCKED SWAB STANDARD 80MM |

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**DECLARACIÓN DE CONFORMIDAD CE  
CE DECLARATION OF CONFORMITY**

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBÍ (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**CONTENEDORES PARA MUESTRAS NO ESTÉRILES**  
**GENERAL SPECIMEN CONTAINER NON-STERILE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de cualquier tipo de muestra para diagnóstico (por ejemplo, orina, heces, esputo, mucosa, tejido) para análisis y/u otra investigación.  
**Intended Use:** Collection and preservation and/or transport, of any type of diagnostic specimen (e.g. urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation.

**Código GMDN / GMDN Code:** 47775

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnóstico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other

José Saez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director

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T: +34 938 363 030 F: +34 938 363 031

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**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS  
ANNEX 1 – ARTICLES DESCRIPTION**

| REF    | DESCRIPCIÓN                              | DESCRIPTION                            |
|--------|------------------------------------------|----------------------------------------|
| 202840 | FRASCO DE SEGURIDAD 20ML                 | SECURITY CONTAINER 20ML                |
| 202841 | FRASCO DE SEGURIDAD 40ML                 | SECURITY CONTAINER 40ML                |
| 202842 | FRASCO DE SEGURIDAD 60ML                 | SECURITY CONTAINER 60ML                |
| 202843 | FRASCO DE SEGURIDAD 90ML (Ø48-h75)       | SECURITY CONTAINER 90ML (Ø48-h75)      |
| 202844 | FRASCO DE SEGURIDAD 120ML                | SECURITY CONTAINER 120ML               |
| 202845 | FRASCO DE SEGURIDAD 250ML                | SECURITY CONTAINER 250ML               |
| 202846 | FRASCO DE SEGURIDAD 500ML                | SECURITY CONTAINER 500ML               |
| 202847 | FRASCO DE SEGURIDAD 1000ML               | SECURITY CONTAINER 1000ML              |
| 202848 | FRASCO DE SEGURIDAD 90ML(Ø53-h68)        | SECURITY CONTAINER 90ML(Ø53-h68)       |
| 300100 | TUBO 17 ML PS 16X150 MM                  | PS TUBE 16X150                         |
| 300101 | TUBO PS 8ML 16X75MM GRADUADO C/BORDE     | PS TUBE 8ML 16X75MM GRADUATED WITH RIM |
| 300300 | TUBO 4 ML PS 11X70 MM                    | TUBE 11X70 PS                          |
| 300400 | TUBO 6 ML PS 12X88 MM GRADUADO           | TUBE 12X88 PS GRADUATED                |
| 300500 | TUBO 3 ML PS 11X55 MM                    | TUBE 11X55 PS                          |
| 300700 | TUBO 13X75 PS                            | TUBE 13X75 PS                          |
| 300702 | TUBO 13X75 PS TAPADO                     | TUBE 13X75 PS CAPPED                   |
| 300704 | TUBO 13X75 PS TAPADO Y ETIQ              | TUBE 13X75 PS CAPPED&LABELLED          |
| 300705 | TUBO 10 ML PS 16X100 MM                  | TUBE 16X100 PS                         |
| 300800 | TUBO 5ML PS 12X75 MM GRADUADO            | TUBE 5ML PS 12X75MM GRADUATED          |
| 300802 | TUBO 12X75 PS + TAPON 305802             | PS TUBE 12X75 + CAP 305802             |
| 300804 | TUBO 12X75 PS TAPADO Y ETIQ              | TUBE 12X75 PS CAPPED LABELLED          |
| 300900 | TUBO 10ML PS 16X95MM GRADUADO            | TUBE 10ML PS 16X95MM GRADUATED         |
| 300903 | TUBO 16x95 PS TAPADO                     | TUBE 16x95 POLYSTYRENE CAPPED          |
| 300904 | TUBO 10 ML PS 16X95 MM TAPADO ETIQUETADO | TUBE 16X95 PS CAPPED LABELLED          |
| 300907 | TUBO 16X100 PS TAPADO                    | TUBE 16X100 PS CAPPED                  |
| 300908 | TUBO 16X100 PS TAPADO Y ETIQ             | TUBE 16X100 PS CAPPED LABELLED         |
| 300911 | TUBO 16X100 PS TAPADO C/308101           | TUBE 16x100 PS CAPPED W/308101         |
| 300912 | TUBO 16X95 PS TAPADO 305002              | 16X95 TUBE PS CAPPED 305002            |

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| REF    | DESCRIPCIÓN                          | DESCRIPTION                     |
|--------|--------------------------------------|---------------------------------|
| 300913 | TUBO 16X95 PS TAPADO                 | TUBE 16X95 PS CAPPED            |
| 300914 | TUBO 16x95 TAPADO 305002             | 16x95 TUBE CAPPED 305002        |
| 301200 | TUBO CONICO 16X102 PS                | CONICAL TUBE 16X102 PS          |
| 301201 | TUBO CONICO 12ML PS 16X100 MM        | CONICAL TUBE 16X100 PS          |
| 301202 | TUBO CONICO 16X102 PS                | CONICAL TUBE 16X102 PS          |
| 301205 | TUBO CONICO 301200 TAP/305502        | PS TUBE 12ML CONICAL CAPPED     |
| 301206 | TUBO CONICO 16X102+TAP.305502        | PS CON. TUBE 16X102 + CAP305502 |
| 301207 | TUBO CONICO 16x102 PS TAPADO         | CONICAL TUBE 16x102 PS CAPPED   |
| 301212 | TUBO CONICO 12 ML PS 17X105 MM       | CONICAL TUBE 17X105 PS          |
| 301213 | TUBO CÓNICO 12ML PS 16X105MM         | CONICAL TUBE 12ML PS 16X105MM   |
| 301403 | TUBO 12ML PS 15X102 MM TAPADO FALDON | TUBE 12ML PS CAPPED             |
| 301700 | TUBO 7 ML PS 13X100 MM               | TUBE 13X100 PS                  |
| 309201 | FRASCO 30ML PS ETIQUETADO            | 30ML UNIVERSAL LABELLED PS      |
| 309202 | FRASCO 30ML PS                       | 30ML CONTAINER PS               |
| 309206 | FRASCO 30ML PS TAPON ROJO            | 30ML PS CONTAINER RED CAP       |
| 309207 | FRASCO 30ML PS TAP.CU SEPARADA       | PS 30ML CONTAINER SEPARATED CAP |
| 309222 | FRASCO 30ML PS B/U                   | 30ML CONTAINER I/W PS           |
| 309402 | FRASCO 40ML PS                       | PS 40ML CONTAINER               |
| 309501 | FRASCO 60ML PS ETIQUETADO            | PS 60 ML CONTAINER PRINTED LBL  |
| 309502 | FRASCO 60ML PS                       | 60ML CONTAINER PS               |
| 309505 | FRASCO 60ML PS T/AZUL                | CONTAINER PS 60ML BLUE CAP      |
| 309552 | FRASCO 60ML PS ESPATULA              | 60ML CONTAINER WITH SPOON PS    |
| 400400 | TUBO 6 ML PP 12X88 MM GRADUADO       | TUBE 12X88 PP GRADUATED         |
| 400500 | TUBO 3 ML PP 11X55 MM                | TUBE 11X55 PP                   |
| 400700 | TUBO 5 ML PP 13X75 MM                | TUBE 13X75 PP                   |
| 400705 | TUBO 10 ML PP 16X100 MM              | TUBE 16X100 PP                  |
| 400800 | TUBO 5ML PP 12X75 MM GRADUADO        | TUBE 5ML PP 12X75MM GRADUATED   |
| 400806 | TUBO 75X12 PP TAPADO T/ROJO          | TUBE 12x75 PP CAPPED 305806     |
| 400900 | TUBO 16X95 PP                        | TUBE 16X95 PP                   |
| 400908 | TUBO 16x95 TAPADO 305007             | 16X95 PP TUBE CAPPED 305007     |
| 401100 | TUBO 5 ML PP 15X50 MM                | TUBE 15X50 PP                   |

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| REF    | DESCRIPCIÓN                          | DESCRIPTION                            |
|--------|--------------------------------------|----------------------------------------|
| 401200 | TUBO CONICO 12 ML PP 16X102 MM       | CONICAL TUBE 16X102 PP                 |
| 401201 | TUBO CONICO 12 ML PP 16X100 MM       | CONICAL TUBE 16X100 PP                 |
| 401202 | TUBO CONICO 16x102+TAPON 16MM        | CONICAL TUBE 16x102 + CAP 16MM         |
| 401204 | TUBO CÓNICO 12ML PP 16X100 MM        | CONICAL TUBE 12ML PP 16X100MM          |
| 401307 | TUBO CONICO 16X102 PP TAPADO         | CONICAL TUBE 16x102 PP CAPPED          |
| 401403 | TUBO 12ML PP 15X102 MM TAPADO FALDON | PP TUBE 13X100                         |
| 401700 | TUBO 7 ML PP 13X100 MM               | PP TUBE 13X100                         |
| 408702 | FRASCO 150 ML PP AL VACÍO            | CUP F/VACUUM COLLECTION 150ml          |
| 408726 | FRASCO 150 ML PP B/U AL VACÍO        | CUP F/VACUUM COLLEC.150ml I/B          |
| 409201 | FRASCO 30ML PP ETIQUETADO            | 30ML CONTAINER LABEL PP                |
| 409202 | FRASCO 30ML PP                       | 30ML CONTAINER PP                      |
| 409222 | FRASCO 30ML PP BOLSA UNITARIA        | 30ML CONTAINER I/W PP                  |
| 409402 | FRASCO 40ML PP GRADUADO              | 40ML CONTAINER PP GRADUATED            |
| 409426 | FRASCO 40ML PP B/U GRADUADO          | 40ML CONTAINER I/W PP                  |
| 409501 | FRASCO 60ML PP ETIQUETADO            | 60ML CONTAINER LABELLED PP             |
| 409502 | FRASCO 60ML PP                       | 60ML CONTAINER PP                      |
| 409507 | FRASCO 60ML PP ROSCADO T/VERDE       | 60ML SCREW CAP CONT PP C/GREEN         |
| 409511 | FRASCO 60ML PP ETIQUETADO T/AZUL     | 60ML BLUE CONTAINER LABEL PP           |
| 409552 | FRASCO 60ML PP C/ESPATULA            | 60ML CONTAINER W/SPOON                 |
| 409556 | FRASCO 60 ML. B/UNIT. CUCHARA        | 60 ML PP CONTAINER WITH SPOON UNIT BAG |
| 409602 | FRASCO 30ML PP C/CUCHARA             | 30ML CONTAINER WITH SPOON PP           |
| 409662 | FRASCO 30ML.T/AZUL CUC S/ROSC        | SCREW CAP CONT.30ml PP                 |
| 409701 | FRASCO 150ML PP ETIQUETADO           | 150ML CONTAINER LABELLED PP            |
| 409702 | FRASCO 150ML PP                      | 150ML CONTAINER PP                     |
| 409703 | FRASCO 150ML PP SIN ROSCAR           | 150ML CONT SEPARATED CAP PP            |
| 409707 | FRASCO 150ML PP T/VERDE              | PP 150 ML CONTAINER GREEN CAP          |
| 409711 | FRASCO 150ML AZUL ETIQUETADO         | 150ML BLUE CONTAINER LABEL PP          |
| 409752 | FRASCO 150ML PP C/CUCHARA            | 150ML CONTAINER WITH SPOON PP          |
| 409756 | FRASCO 150ML B/U ESPATULA PP         | 150ML CONTAINER I/W SPOON PP           |
| 409802 | FRASCO 50ML PP                       | 50ML CONTAINER PP                      |
| 409826 | FRASCO 50ML PP B/U                   | 50ML CONTAINER I/W PP                  |

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| REF       | DESCRIPCIÓN                         | DESCRIPTION                        |
|-----------|-------------------------------------|------------------------------------|
| 409852    | FRASCO 50ML PP CON ESPATULA         | 50ML CONTAINER WITH SPOON PP       |
| 409902    | FRASCO 200ML PP                     | 200ML CONTAINER PP                 |
| 409905    | FRASCO 200ML PP AZUL TRANS. ETI     | CONTAINER 200 ML PP BLUE-PLAIN LBL |
| 409915    | FRASCO 200ML PP AZUL TRANS S/E      | CONTAINER 200 ML PP BLUE           |
| 409926    | FRASCO 200ML PP B/U                 | 200ML CONTAINER PP I/W             |
| 410046    | FRASCO 50 ML PP T/PRECINTO          | TAMPER EVIDENT CONT.50ml H80mm     |
| 410047    | FRASCO T/BISAGRA 50ml H=80mm        | HINGED LID CONT.50ml H=80mm        |
| 410056    | FRASCO PRECINTO 50ml H80mm B/U      | HINGED LID CONT.50ml H80mm I/B     |
| 419802    | FRASCO 50ML PP T/PRECINTO           | 50ML CONT SEALED CAP PP            |
| 419805    | FRASCO 50ML PP T/PRECÍ AZUL         | PP 50 ML CONT. SEALED CAP BLUE     |
| 419825    | FRASCO 50ML PP T/PREC.AZUL B/U      | 50ML CONT SEAL.BLUE CAP I/W PP     |
| 419826    | FRASCO 50ML PP T/PRECINTO B/U       | 50ML CONT SEALED CAP I/W PP        |
| 429900    | TUBO CONICO 50 ML PP TAPADO         | 50ML CONICAL TUBE PP               |
| 429901    | TUBO CONICO 50ML PP FALDON TAPADO   | 50ML CONICAL TUBE SKIRT PP         |
| 429903    | TUBO 50ML PP CON.FALDON S/TAP       | 50ML CON.TUBE SKIRTE PP NO CAP     |
| 429910    | TUBO CONICO 15ML PP TAPADO          | 15ML CONICAL TUBE PP               |
| 444602801 | FRASCO DE SEG. 60ML T/AZUL          | CHILD PROOF CONT 60ML BLUE LID     |
| 444602802 | ANTI-CHILD. SIN TAPON               | CHILD PROOF CONT.60ML NO CAP       |
| 444602901 | FRASCO SEGURIDAD 60ML T/AZUL        | CHILDPROOF CONT 60ML BLUE LID      |
| 444602903 | ANTI-CHILD BLANCO T/BLANCO 60       | CHILD PROOF WHITE CONTAINER 60     |
| 444603202 | FRASCO DE SEG. 30ML T/BLAN PRECINTO | SECURITY CONT. 30ML WHITE CAP      |
| 444603204 | F.SEGURIDAD BLANCO 30ML T/BLANCO    | CHILDPROOF WH.CONT 30ML B/CAP      |
| 444603300 | FRASCO SEGURIDAD 60ML T/BLANCO      | CHILDPROOF CONT 60ML WHITE LID     |
| 444603305 | ANTI-CHILD.AZUL TAPON BLANCO        | CHILD PROOF BLUE CONT.WHIT CAP     |
| 444603306 | ANTI-CHILD. VERDE TAPON BLANCO      | CHILD PROOF GREEN CONT.WHIT CAP    |
| 444603308 | ANTI-CHILD.ROJO TAPON BLANCO        | CHILD PROOF RED CONT.WHIT CAP      |
| 444603402 | F. SEGURIDAD 125ML T/BLANCO         | CHILDPROOF CONT 125ML WHITE LID    |
| 202845N   | TARRO HISTOLOGIA 250ML. NEGRO       | HISTOLOGY CONTAINER 250ML BLACK    |
| 202846/T  | FRASCO DE SEGURIDAD 500ML TAPADO    | SECURITY CONTAINER 500ML CAPPED    |
| 202847/T  | FRASCO DE SEGURIDAD 1000ML TAPADO   | SECURITY CONTAINER 1000ML CAPPED   |

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| REF       | DESCRIPCIÓN                            | DESCRIPTION                        |
|-----------|----------------------------------------|------------------------------------|
| 300500.8  | TUBO 11X55 PS                          | TUBE 11X55 PS                      |
| 300800.1  | TUBO 5 ML PS 12X75 MM SIN ENRASES      | TUBE 12X75 PS                      |
| 300800.2  | TUBO 12X75 PS REFORZADO                | TUBE 12X75 PS                      |
| 300900M   | TUBO 16X95 PS GRAD.CAJA 5X100          | TUBE 16X95 PS GRAD.CASE 5X100      |
| 309202.4  | FRASCO 30ML PS                         | PS 30 ML. UNIVERSAL PLAIN LBL      |
| 309202.NR | FRASCO 30ML PS                         | 30ml CONTAINER PS NO SCREW         |
| 309202V   | FRASCO 30ML PS TAPÓN VERDE             | 30ML CONTAINER PS GREEN CAP        |
| 309202.WO | FRASCO 30ML PS SIN TAPÓN               | CONT.30ML PS NO CAP                |
| 309222.1  | FRASCO 30ML PS B/U ETIQUETADO          | CONTAINER 30 ML. UNIT BAG LABEL    |
| 309501BE  | FRASCO 60ML PS B/50 CÓD. BARRAS        | 60ML PS CONTAINER B/50 BAR COD     |
| 309502.10 | FP-60 S/ROSCAR C/600 T/ROJO            | CONT.60ML C/600 RED CAP            |
| 309502.6  | FRASCO 60 ML. PS ETIQUETA BLANC        | PS 60 ML. CONTAINER PLAIN LABEL    |
| 309602E   | FRASCO 30ML PS CON ESPATULA ETIQUETADO | 30ML CONTAINER WITH SPOON PS       |
| 309622.1  | FCO.30 CUCH. ETIQ. ESP. B/UNIT.        | PS 30ML SPOON+LABEL+UNIT BAG CONT. |
| 400004.1  | FRASCO 125ML PP 57X73                  | 125ML CONTAINER PP                 |
| 400500.B  | TUBO 11x55 PP B/400                    | TUBE 11x55 PP B/400                |
| 400706E   | TUBO 10ML C/A.BORICO TAP.ETIQ.B/U      | 100ML TUBE W/BORIC A. CAP.LAB. I/W |
| 400800.1  | TUBO 5 ML PP 12X75 MM SIN ENRASES      | TUBE 12X75 WITHOUT RINGS PP        |
| 400906BOR | TUBO 16X100 TAP- 308106 AC. BOR        | TUBE 16x100 PP CAP ACID BORIC      |
| 400906MD  | TUBO 16x100 PP TAPADO 308106           | 16x100 TUBE PP CAPPED 308106       |
| 409201.S  | FRASCO 30ML PP ETIQUETADO              | 30ML CONTAINER LABEL PP            |
| 409201.SE | FRASCO 30ML PP ETIQUETADO B100         | 30ML CONTAINER LABEL PP B/100      |
| 409202.8  | FRASCO 30 ML TAPADO TAPON AZUL         | 30ML CONTAINER PP BLUE CAP         |
| 409202.WO | FRASCO 30ML PP SIN TAPÓN               | CONT. 30ML PP NO CAP               |
| 409203.2  | FRASCO 30ML PP T/BLAN ENV. SEP         | PP 30 ML+ WHITE CAP SEPARAT.C/1800 |
| 409203.2A | FR.30ML PP T/BL.ENV.SEP.C/ANO          | PP 30ML WHITE CAP SEP.PLAIN BO     |
| 409502.2B | FR.60ML ETIQ.T/ROJO 10X50              | CONT.60ML LABEL RED C.10X50        |
| 409502.2C | FR. 60ML PP ETIQ.T/ROJO 16X50          | 60ML CONT. PP LABEL RED CAP 16X50  |
| 409502.4  | FRASCO 60ML S/ROSCAR 38X65 PP          | 60ML CONT. UNCAPPED 38X65MM PP     |
| 409502.4Y | FRASCO 60ml S/ROSCAR PP T/AMA          | 60ml CONT.UNCAPPED PP YEL/LID      |
| 409502G   | FRASCO 60ML GRADUADO                   | 60ML CONTAINER GRADUATED PP        |

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| REF       | DESCRIPCIÓN                         | DESCRIPTION                          |
|-----------|-------------------------------------|--------------------------------------|
| 409502G.4 | FR.60 GRAD.S/ROSCAR TAP.SEPARA      | CONT.60 GRAD.UNCAPPED SEP.CAP        |
| 409507G   | FRASCO 60ml PP GRAD.T/VERDE         | 60ml CONT.PP GRAD.GREEN CAP          |
| 409511.4  | FR.60ML AZUL CLARO S/ETIQUETA       | 60ML LIGHT BLUE CONTAINER            |
| 409511.5  | FR.60ML AZUL TRANS.L ETIQ. BLANC    | 60ML CONTAINER TRANS.BLUE LBL        |
| 409552.Y  | FRASCO 60ml PP C/ESPÁTULA T/AM      | 60ml CONTAINER W/SPOON YEL/LID       |
| 409552G   | FRASCO 60ML PP GRADUADO C/ESPA      | 60ML CONTAINER W/SPOON GRADUAT       |
| 409552.TA | FRASCO 60ML PP C/ESPATULA T.AZUL    | 60ML CONTAINER PP W/SPOON BLUE CAP   |
| 409702.3  | FRASCO 150ml PP TAPÓN BLANCO        | PP CONTAINER 150ml WHITE CAP         |
| 409702.P  | FRASCO 150ML PP ROSCADO             | 150ML PP CUPPED CONTAINER            |
| 409702.PB | FRASCO 150ML PP ROSCADO T.BLA       | 150ML PP CUPPED CONT.WHYTE C.        |
| 409703.5  | FRASCO 150 ML. T/AZUL S/ROSCAR      | 150ML CONT SEPARATED BLUE CAP        |
| 409703WC  | FRASCO 150ML PP SIN ROSCAR T/BLANCO | 150ML PP CONT.SEPAR.CAP WHITE        |
| 409711.4  | FR.150ML AZUL CLARO S/ETIQUETA      | 150ML LIGHT BLUE CONTAINER           |
| 409711.5  | FR.150ML AZUL TRANS. ETIQ. BLANC    | 150ML CONTAINER BLUE TRANS.LB        |
| 409805.6  | FRASCO 50ML PP T/ROJO SEPARADO      | 50ML PP CONTAINER SEP. RED CAP       |
| 410046.5  | FRASCO T/PREC.50ml H80mm C/500      | HINGED LID CONT.50ml H80 C/500       |
| 410046A.5 | FRASCO T/PREC.50ml 500UD AZUL       | HINGED LID CONT.500U BLUE            |
| 410046R.5 | FRASCO T/PREC.50ml 500UD ROSA       | HINGED LID CONT.500U PINK            |
| 420900E   | TUBO 12ML PP S/TAPON C/FALDON       | PP 12ML TUBE W/SKIRT W/OUT CAP       |
| 429900.25 | TUBO CONICO 50ml PP B/25            | 50ml CONICAL TUBE PP B/25            |
| 429900SP  | TUBO 50ML PP CONICO SIN ROSCAR      | 50ML CONICAL TUBE PP SEP.CAP         |
| 429901.25 | TUBO CON.50ml PP C/FALDON B/2       | 50ml CONICAL TUBE W/SKIRT B/25       |
| 429910SP  | TUBO 15ml PP CONICO SIN ROSCAR      | 15ml CONICAL TUBE PP SEP.CAP         |
| 429927S/E | TUBO CONICO 50ML C/FALDON B/U       | 50ML CONICAL TUBE SKIRT I/W PP       |
| 44462903M | ANTI-CHILD BLANCO T/BLANCO 60       | CHILDPPOOF WHIE CONT.60ML WC         |
| 309202.O  | FRASCO 30ML PS ST. EO               | CONTAINER 30ML PS ST.EO              |
| 429930    | TUBO 50ML PP CONICO IMPRESO B/25    | 50ML TUBE PP CONICAL PRINT 25/B      |
| 429940    | TUBO 15 ML PP CONICO IMPRESO GRANEL | 15ML TUBE PP CONICAL PRINTED IN BULK |
| 429945    | TUBO 15 ML PP CONICO IMPRESO B/25   | 15ML TUBE PP CONICAL PRINT 25/B      |

Fecha / Date: 17/01/2017  
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| REF        | DESCRIPCIÓN                           | DESCRIPTION                                |
|------------|---------------------------------------|--------------------------------------------|
| 429950     | TUBO 50 ML PP CONICO IMPRESO C/F B/25 | 50ML TUBE PP CONICAL PRINT SKIRTED 25/B    |
| 300500MI   | TUBO 11X55 PS                         | TUBE 11X55 PS                              |
| 175723     | TUBO 5ML PS 13X75 TAPADO ROJO         | TUBE 5ML PS 13X75 CAPPED RED               |
| 175724     | TUBO 10ML PS 16X95 TAPADO ROJO        | 10ML TUBE PS 16X95 CAPPED RED              |
| 400903     | TUBO 10ML PP 16X95 TAPADO ROJO        | 10ML TUBE PP 16X95 CAPPED RED              |
| 661035     | TUBO 10ML PS 16X95 TAPADO NATURAL     | 10ML TUBE PS 16X95 CAPPED NATURAL          |
| 408702C    | FRASCO VACÍO 120ml LOTE IMPRESO       | VACUUM CONT.120ML CML                      |
| 408726.A   | FRASCO P/VACÍO 120ml B/I C/AN.        | CUP F/VACUUM 120ml I/B PLAIN/C             |
| 400805     | TUBO 75X12 PP TAPADO T/AZUL           | TUBE 75X12 PP CAPPED C/B/LUE               |
| 202844/T   | FRASCO DE SEGURIDAD 120ML TAPADO      | SECURITY CONTAINER 120ML CAPPED            |
| 409557     | FRASCO 60ML PP C/ESPATULA T/VERDE     | CONTAINER 60ML PP W/SPOON GREEN CAP        |
| 419802.T   | FRASCO 50ML PP T/PREC. DESTAPADO      | CONTAINER 50ML PP C/TAMPER EVID. UNCOVERED |
| 409502.4B  | FRASCO 60ML PP T/AZUL NO TAPADO       | 60ML CONTAINER PP BLUE CAP UNCOVERED       |
| 409702B    | FRASCO 150ML PP B/50                  | 150ML CONTAINER PP B/50                    |
| 309205     | FRASCO 30ML PS T/AZUL ETIQ.           | 30ML CONTAINER PS BLUE CAP LABEL           |
| 429906SP   | TUBO 50ML PP CONICO T/ROJO SIN ROSCAR | 50ML CONICAL TUBE PP SEP.CAP RED           |
| 429901SP   | TUBO CONICO 50ML PP FALDON SIN ROSCAR | TUBE 50ML PP SKIRTED SEP. CAP              |
| 175725     | TUBO 3ML PS 11X55 TAPADO ROJO         | TUBE 3ML PS 11X55 CAPPED RED               |
| 409511.4TA | FRASCO 60ML PP C/CUCHARA T/AZUL       | CONTAINER 60ML PP W/SPOON BLUE CAP         |
| 202842A    | FRASCO SEGURIDAD 60ML T/AZUL          | CONTAINER 60ML BLUE CAP                    |
| 202844A    | FRASCO DE SEGURIDAD 120ML T/AZUL      | SECURITY CONTAINER 120ML BLUE CAP          |
| 409512     | FRASCO 60ML PP T/ROJO C/GRIS          | CONT. 60ML PP RED C. GREY B.               |
| 301201CA   | TUBO CONICO 12ML PS 16X100 MM         | CONICAL TUBE 16X100 PS                     |

Fecha / Date: 17/01/2017  
Pag. 8/8

CDCE-14 Rev.13.15

## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**TUBOS DE EXTRACCIÓN – CITRATO TAMPONADO**  
**BLOOD CONTAINERS – SODIUM CITRATE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (p.ej. para estudios de coagulación del plasma)  
**Intended Use:** Collection and preservation and/or transport, of blood for analysis and/or other (e.g. for plasma coagulation studies)

**Código GMDN / GMDN Code:** 58139

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnostico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other

  
José Saez  
Director General / Managing Director

  
Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 21/11/2013  
Pag. 1/2

CDCE-79 Rev.1

## ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF      | DESCRIPCIÓN                    | DESCRIPTION                    |
|----------|--------------------------------|--------------------------------|
| 601102   | TUBO CITRATO PP 4 ML           | CITRATE TUBE 4ML PP            |
| 601103   | TUBO CITRATO PP 2,5ML          | CITRATE TUBE 2.5ML PP          |
| 601203   | TUBO CITRAT TAMP 3,2% PP 2,5ML | CITRATE TUBE 3.2% 2.5ML PP     |
| 621101   | TUBO CITRATO 1ML PERFORABLE    | CITRATE TUBE 1ML PIERCEABLE    |
| 621102   | TUBO CITRATO 2ML PERFORABLE    | CITRATE TUBE 1ML PIERCEABLE    |
| 601103.2 | TUBO CITRATO 2.5ML RETRACTIL   | CITRATE TUBE 2.5ML WRAPPEDRACK |
| 601203.1 | TUBO CITRATO 3.2% 2.5ML GRANEL | CITRATE TUBE 3.2% 2.5ML BULK   |

Fecha / Date: 21/11/2013  
Pag. 2/2

CDCE-79 Rev.1



# DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Liana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
*Declares under its responsibility that the product:*

**TUBOS DE EXTRACCIÓN – K3EDTA**  
**BLOOD CONTAINERS – K3EDTA**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, hematología de sangre como conteo sanguíneo completo (SCS), y determinación cuantitativa de drogas.

**Intended Use:** Collection and preservation and/or transport of blood for analysis and/or other investigation (e.g. whole blood hematology such as complete blood count (CBC) and quantitative drug assay determinations).

**Código GMDN / GMDN Code:** 58143

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnóstico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other



José Sáez  
Director General / Managing Director



Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
Pag. 1/2

CDCE-77 Rev.2

# ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF      | DESCRIPCIÓN                                  | DESCRIPTION                                   |
|----------|----------------------------------------------|-----------------------------------------------|
| 601603   | TUBO EDTA TRIPOTASICO 2,5ML PP 13X75MM       | EDTA TUBE TRI-K R/BOT 2.5ML PP                |
| 601612   | TUBO EDTA TRI-K PP 4ML                       | EDTA TUBE TRI-K 4ML PP                        |
| 601613   | TUBO EDTA TRI-K PP 2,5ML                     | EDTA TUBE TRI-K 2.5ML PP                      |
| 601702   | TUBO EDTA TRI-K PP 4ML                       | EDTA TUBE TRI-K 4ML PP                        |
| 611604   | TUBO EDTA TRI-K 3ML PP 13X80 T/GOMA PERF.    | EDTA TRI-K TUBE 3ML PP 13X80 RUBBER CAP PERF. |
| 621610   | TUBO EDTA TRI-1ML PP 12X55MM T/PRE PERF.     | EDTA TUBE TRI-K 1ML PP 12X55MM C/PRE-PERF.    |
| 621611   | TUBO EDTA TRI-K 2ML 16X55 FALDON T/PRE-PERF. | EDTA TUBE TRI-K 2ML 16X55 SKIRTED C/PRE-PERF. |
| 621613   | TUBO EDTA TRI 2,5ML PP 13X80MM T/PERFOR.     | EDTA TUBE TRI-K 2.5ML PP 13X80MM T/PRE-PERF.  |
| 601603.2 | TUBO EDTA TRI-K 2.5ML RETRACTILADO           | EDTA TRI-K TUBE 2.5ML WRAPP/RAC               |
| 601702.2 | TUBO EDTA TRI-K 4ML RETRACTILADO             | EDTA TRI-K TUBE 4ML WRAPP/RACK                |
| 611603.1 | TUBO EDTA TRI-K PULV. 3ML 13X75 T/PERFO      | EDTA TUBE PUL.K3 3ML PIERC.CAP                |

Fecha / Date: 20/06/2016  
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CDCE-77 Rev.2.2

# DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Liana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
*Declares under its responsibility that the product:*

**TUBOS DE EXTRACCIÓN – SEROTUB**  
**BLOOD CONTAINERS – SEROTUBE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, determinación química del suero sanguíneo).

**Intended Use:** Collection and preservation and/or transport, of blood for analysis and/or other investigation (e.g. blood serum chemistry determinations)

**Código GMDN / GMDN Code:** 58138

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnóstico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other



José Sáez  
Director General / Managing Director



Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
Pag. 1/2

CDCE-45 Rev.10

# ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF    | DESCRIPCIÓN                   | DESCRIPTION                    |
|--------|-------------------------------|--------------------------------|
| 600300 | TUBO SUERO PP 9ML GRANULOS    | SEROTUBE W/GRANULES PP 9ML     |
| 600400 | TUBO SUERO PP 4ML GRANULOS    | SEROTUBE W/GRANULES PP 4ML     |
| 600602 | SEROTUB GLUCOSA PP 4ML        | SERUM GLUCOSE 4ML GRANULES PP  |
| 600610 | SEROTUB GLUCOSA PP 10ML       | PP SERUM GLUCOSE 10ML GRANULES |
| 600800 | TUBO SUERO PP 9ML GEL         | SERUM TUBE W/GEL 9ML PP        |
| 600801 | TUBO SUERO PP 4ML GEL         | SERUM TUBE W/GEL 4ML PP        |
| 620200 | TUBO SUERO 2ML PERF GRANULOS  | SERUM TUBE 2ML PIER W/GRANULES |
| 620300 | TUBO SUERO 10ML PERF GRANULOS | SERUM TUBE 10ML PIER W/GRANULE |
| 620400 | TUBO SUERO 4ML PERF GRANULOS  | SERUM TUBE 4ML PIER W/GRANULES |
| 620800 | TUBO SUERO 10ML PERF GEL      | SERUM TUBE 10ML PIERCEABLE GEL |

Fecha / Date: 22/11/2013  
Pag. 2/2

CDCE-45 Rev.10



Certificate ES10/81671

The management system of

**DELTALAB, S.L.**

Polígono Industrial La Llana, Plaza De La Verneda 1,  
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**  
**EN ISO 13485:2016**



For the following activities

**Design, manufacture and sale of sterile and nonsterile medical devices  
for the collection, transport and conservation of biological samples for  
clinical and IVD analysis.**

**Distribution of non-active medical devices and in vitro diagnostic  
medical devices.**

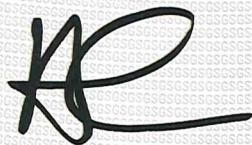
**Diseño, fabricación y comercialización de productos sanitarios  
estériles y no estériles para la toma, transporte y conservación de  
muestras biológicas para análisis clínicos y de IVD.**  
**Distribución de productos sanitarios no activos y productos sanitarios  
para diagnóstico in vitro.**

This certificate is valid from 11 October 2019 until 11 October 2022  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 September 2022

Issue 9. Certified since 12 October 2010

Authorised by




0005

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
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Page 1 of 1



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Certificate ES16/20725

The management system of

**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

Pol. Ind. La Llana  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

has been assessed and certified as meeting the requirements of

**ISO 9001:2015**

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis, general labware, containers and healthcare products. Manufacture and commercialization of consumables for the laboratory. Commercialization and distribution of equipment for the storage of prepared samples, cryogenic stored samples, syringes, general labware and industrial packages. Commercialization and distribution of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes. Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

This certificate is valid from  
11 October 2019 until 11 October 2022.  
Issue 4. Company certified since October 2010.  
Certified with SGS since 11 October 2016.

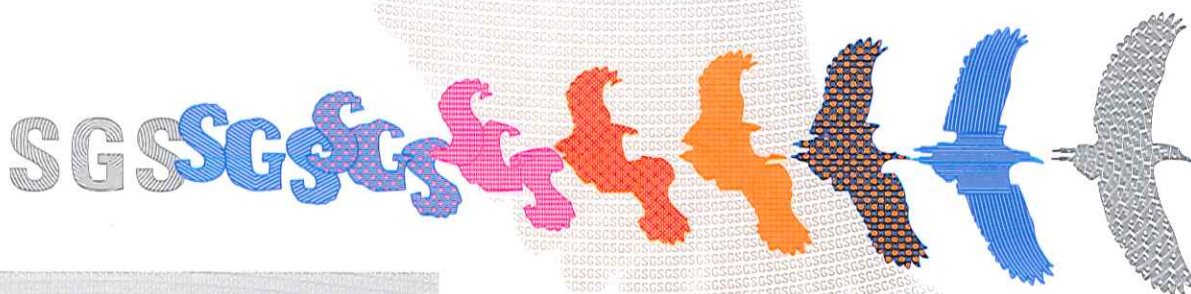
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Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.  
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**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

**ISO 9001:2015**

Issue 4



Sites where these activities are totally or partially carried out

**DELTALAB, S.L.**

Pol. Ind. La Llana, Plaza de la Verneda, 1 – 08191 Rubí, Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

**KEYLAB, S.L.U.**

Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

**NIRCO, S.L.**

Pol. Ind. Expansión, Puerto de Navafria, 12 - 28935 Móstoles -Madrid (España)  
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Manufacture and commercialization of consumables for the laboratory.

Commercialization and distribution of diagnostic kits

Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

**ENVASES FARMACÉUTICOS, S.A.**

C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Design, manufacture and commercialization of laboratory material for the collection, transport and conservation of samples for analysis, laboratory material for general use, containers and products for personal care

Commercialisation and distribution of laboratory material for general use, products and equipment for personal care, syringes and cosmetic products.





# DELTALAB, S.L.

Pol. Ind. La Llana  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP  
certified organization as meeting the requirements of

## ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection,  
transport and conservation of samples for microbiological, molecular biology,  
hematology, biochemistry, histology, microscopy and colorimetric analysis.  
Commercialization of equipment for the storage of prepared samples,  
cryogenic stored samples, general labware and industrial packages.  
Commercialization of equipment and instrumentation for the laboratory,  
diagnostic kits, healthcare products, cosmetics and food for  
special medical purposes.

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubí (Barcelona)

Valid from  
11 October 2019 until 11 October 2022.

Issue 1.

This document is part of Certificate ES16/20725.  
The validity of this document is subject to the certificate.

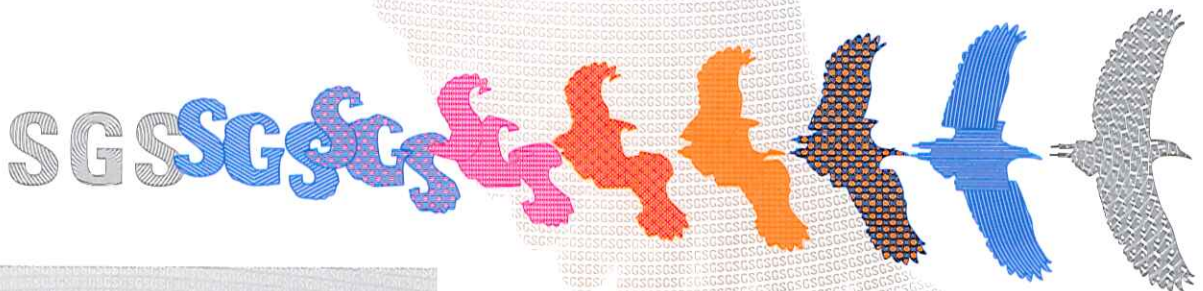


Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.  
C/Trespaderne, 29. 28042 Madrid. España.  
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

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Document No.: **DC-002**

Rev. 10

DoC Release Date. 4/26/2017

Page 1 of 4

## **DECLARATION OF CONFORMITY**

**Manufacturer:**

**Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
Cincinnati, Ohio 45241-1528**

**EC Representative:**

**CEpartner4U B.V.  
Esdoornlaan 13  
3951 DB Maarn  
The Netherlands**

**Warehouse:**

**7100 Dixie Highway  
Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| <b>Product name</b>                               | <b>Description</b>                | <b>Model number</b> | <b>CSZ Part #</b> | <b>First date of CE-marking</b> |
|---------------------------------------------------|-----------------------------------|---------------------|-------------------|---------------------------------|
| FilteredFlo <sup>®</sup> Warming Tube             | 28" x 66" (71.1cm x 167.6cm)      | 145                 | 82145             | 1998-01                         |
| FilteredFlo <sup>®</sup> Adult Full Body Blanket  | 92" x 50" (233.71cm x 127cm)      | 243                 | 82243             | 2003-08                         |
| FilteredFlo <sup>®</sup> Adult Full Body Blanket  | 92" x 50" (233.71cm x 127cm)      | 243                 | 83243             | 2003-08                         |
| FilteredFlo <sup>®</sup> Pediatric Blanket        | 55" x 40" (139.7cm x 101.6cm)     | 244                 | 82244             | 2003-08                         |
| FilteredFlo <sup>®</sup> Pediatric Blanket        | 55" x 40" (139.7cm x 101.6cm)     | 244                 | 83244             | 2003-08                         |
| FilteredFlo <sup>®</sup> Infant Underbody Blanket | 44.5" x 29.75" (113 cm x 75.6 cm) | 246                 | 82246             | 2005-11                         |
| FilteredFlo <sup>®</sup> Torso Blanket            | 43" x 40" (109.2cm x 101.6cm)     | 344                 | 82344             | 2003-08                         |
| FilteredFlo <sup>®</sup> Torso Blanket            | 43" x 40" (109.2cm x 101.6)       | 344                 | 83344             | 2003-08                         |
| FilteredFlo <sup>®</sup> Lower Body Blanket       | 58" x 40" (134.6cm x 101.6cm)     | 442                 | 82442             | 2003-08                         |
| FilteredFlo <sup>®</sup> Lower Body Blanket       | 58" x 40" (134.6cm x 101.6cm)     | 442                 | 83442             | 2003-08                         |

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Template # 0622.10

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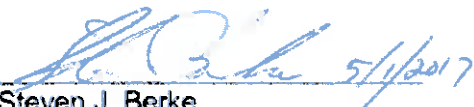
Document No.: DC-002

Rev. 10

DoC Release Date. 4/26/2017

Page 2 of 4

| Product name                         | Description                     | Model number | CSZ Part # | First date of CE-marking |
|--------------------------------------|---------------------------------|--------------|------------|--------------------------|
| FilteredFlo® Upper Body Blanket      | 88" x 30" (223.5cm x 76.2cm)    | 443          | 82443      | 2003-08                  |
| FilteredFlo® Sterile Cardiac Blanket | 72" x 50" (182.8cm x 127cm)     | 542          | 82542      | 2004-05                  |
| FilteredFlo® Adult Underbody Blanket | 78.5" x 40" (199.4cm x 101.6cm) | 248          | 82248      | 2013-03                  |
| FilteredFlo® Lower Body Blanket      | 46" x 36" (116.8cm x 91.4cm)    | 460          | 82460      | 2014-07                  |
| FilteredFlo® Upper Body Blanket      | 76" x 24" (193.0 x 61cm)        | 461          | 82461      | 2015-02                  |
| FilteredFlo® Adult Full Body Blanket | 80" x 36" (203.2 x 91.4cm)      | 462          | 82462      | 2015-02                  |

  
Steven J. Berke  
President / CEO

  
Christina M. Miracle  
Manager of Regulatory Compliance



|                                                                                                                |                             |             |
|----------------------------------------------------------------------------------------------------------------|-----------------------------|-------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.: <b>DC-002</b> | Rev. 10     |
|                                                                                                                | DoC Release Date: 4/26/2017 | Page 3 of 4 |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Medical Devices – Quality management systems - Requirements regulatory purposes- Technical Corrigendum 1                                                                                                       |
| EN ISO 10993-1:2009        | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.                                                                                                    |
| EN ISO 10993-7:2008        | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals                                                                                                                      |
| EN ISO 11135-1:2007        | Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices                                   |
| EN ISO 14971:2012          | Medical Devices- Application of risk management to medical devices                                                                                                                                             |
| EN 60601-1-6:2010          | Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability                                                                      |
| ISTA 1C:2014               | International Shipping Standards - Non-Simulation Integrity Performance Test Procedure                                                                                                                         |
| EN ISO 11607-1:2009        | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems                                                                        |
| EN ISO 11607-2:2006        | Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes                                                                             |
| IEC 60601-1:2005, A1: 2012 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                                                         |
| EN 60601-2-35:2009         | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| EN 1041:2008               | Information supplied by the manufacturer of medical devices                                                                                                                                                    |
| EN 980: 2008               | Symbols for use in the labelling of medical devices                                                                                                                                                            |
| ISO 15223-1:2012           | Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.                                                                                                     |

**References:**

CE-Certificate Number: 66692CE03

CSZ Tech File Number: CETF- 243



Christina M. Miracle  
Manager of Regulatory Compliance





Document No.; DC-002

Rev. 10

DoC Release Date. 4/26/2017

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**Revision History:**

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 01       | Updated DoC from revised template from 0622.3 to 0622.5. Added Underbody blanket, CAT# 248. Added ISO 11607-1:2006 and ISO 11607-2:2006 to Applied standards.                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2        | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added PACU Pediatric Blanket # 244 to Product List. Deleted IEC 60601-2-35:1996 Standard. Added IEC 60601-1:2005 , IEC 80601-2-35:2009, BS EN 980:2008 and BS EN 1041:2008 to Applied Standards. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010 in Applied Standards. Updated ISO 14971:2007 to ISO 14971:2012. Corrected the Template callouts in Revision 01 Change Block to 0622.3 and 0622.5. Simplified Date of standard for ISO 13485:2003. |
| 3        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. Added 82460 to list of blankets.                                                                                                                                                         |
| 4        | Updated product name on Page 1 to include the FilteredFlo name.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 5        | Added Cat #461 and #462 to the list of blankets. Approval changed to Manager of Regulatory Compliance.                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 6        | Modified description and product name of Infant blanket, Cat #246.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 7        | Updated ISTA standard. Updated title and descriptions of standards. Removed ASTM-F2196-02:2002 standard. Replaced ISO 15223 with EN 980 standard. Updated to current template.                                                                                                                                                                                                                                                                                                                                                                                |
| 8        | Added P/N 83442.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 9        | Added P/N 83244. Updated dimensions of Cat #244.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 10       | Added ISO 15223-1:2012 standard. Added P/Ns 83243, and 83344.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |





Document No.: DC-005

Rev. 4

DoC Release Date: 7/20/2016

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## DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
Cincinnati, Ohio 45241

EC Representative:

CEpartner4U B.V.  
Esdoornlaan 13  
3951 DB Maarn  
The Netherlands

Warehouse:

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name | Description                                         | Model number | CSZ Part # | First date of CE-marking |
|--------------|-----------------------------------------------------|--------------|------------|--------------------------|
| WarmAir 135  | Convective Warming Device                           | 135          | 86187      | 1999-09                  |
| WarmAir 135  | Convective Warming Device with British Leading Cord | 135          | 86188      | 2012-08                  |



Steven J. Berke  
President



Christina M. Miracle  
Manager of Regulatory Compliance





Document No.: DC-005

Rev. 4

DoC Release Date: 7/20/2016

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**Applied standards in full or in part:**

| <b><u>Standard No.</u></b>           | <b><u>Title</u></b>                                                                                                                                                                                            |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003                       | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                            |
| EN ISO 14971:2012                    | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                             |
| EN 60601-1-6:2010                    | Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability                                                                                |
| EN 60601-1-2:2007                    | Medical electrical equipment- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility requirements and tests                                                             |
| IEC 60601-1:1988, AM1:1991, AM2:1995 | Medical electrical equipment- Part 1 - General requirements for safety                                                                                                                                         |
| ASTM-F2196-02:2002                   | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices                                                                                                            |
| ISTA 1C:2001                         | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                                         |
| IEC 60601-1:2005/A1:2012             | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                                                         |
| EN 80601-2-35:2009                   | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| EN 980:2008                          | Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied                                                                                                      |
| EN 1041:2008                         | Information supplied by the manufacturer of medical devices                                                                                                                                                    |

**References:**

CE-Certificate Number: 66692CE01

CSZ Tech File Number: CETF- 135

Christina M. Miracle  
Manager of Regulatory Compliance





Document No.; DC-005

Rev. 4

DoC Release Date: 7/20/2016

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### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                     |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration. Previously Form #0647.15.                                                                                                                                                                                                                                                                                                                                                           |
| 1        | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added IEC 60601-1:2005, IEC 80601-2-35 and BS EN1041 standards to the Applied Standards. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010. Updated IEC IEC 60601-1-2:2004 to IEC 60601-1-2:2007. Removed the Universal Stand (#91505) from the CETF. Updated ISO 14971:2007 to ISO 14971:2012. |
| 2        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Added IEC 60601-1-2:2004. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement.           |
| 3        | Added 86188 WarmAir with british leading cord to listed products table. Updated DoC template form 0622.7 to 0622.9.                                                                                                                                                                                                                                                                                      |
| 4        | Updated DoC template form 0622.9 to 0622.10. Removed IEC and BS from standards.                                                                                                                                                                                                                                                                                                                          |





Document No.; DC- 006

Rev. 3

DoC Release Date. *May 23, 2016*

Page 1 of 3

## DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
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CEpartner4U B.V.  
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3951 DB Maarn  
The Netherlands

Warehouse:

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name                   | Description                  | Model number | CSZ Part # | First date of CE-marking |
|--------------------------------|------------------------------|--------------|------------|--------------------------|
| Norm-O-Temp 111W               | Hyperthermia System          | 111W         | 86158      | 1998-01                  |
| Norm-O-Temp Stand with IV Pole | Stand with IV Pole           | 118          | 52301      | 1998-01                  |
| Norm-O-Temp Low Profile Stand  | Low Profile Stand            | 119          | 52302      | 1998-01                  |
| 9' Reusable Hose               | 9' Reusable Connecting Hose  | 286          | 91824      | 1998-01                  |
| 27' Reusable Hose Extension    | 27' Reusable Extension Hose  | 287-27       | 91831      | 2015-11                  |
| 18' Reusable Hose              | 18' Reusable Connecting Hose | 286-18       | 91840      | 1998-01                  |
| 27' Reusable Hose              | 27' Reusable Connecting Hose | 286-27       | 91841      | 1998-01                  |

  
Steven J. Berke  
President / CEO

  
Christina M. Miracle  
Manager of Regulatory Compliance

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| <br><b>A GENTHERM COMPANY</b> | Document No.; DC- 006                 | Rev. 3      |
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**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                |
| EN ISO 14971:2012          | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                 |
| EN 60601-1-6:2010          | Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability                                                                    |
| EN 60601-1-2:2007          | Medical electrical equipment- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility requirements and tests                                                 |
| EN 80601-2-35: 2009        | Medical electrical equipment: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| IEC 60601-1:2005: A1: 2012 | Medical electrical equipment – Part 1: general requirements for basic safety and essential performance.                                                                                            |
| ASTM-F2196-02:2002         | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices                                                                                                |
| ISTA 1C:2001               | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                             |
| ISO 15223-1:2012           | Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.                                                                                          |
| EN 980:2008                | Symbols used in the labelling of medical devices.                                                                                                                                                  |
| EN 1041:2008.              | Information supplied by the manufacturer of medical devices                                                                                                                                        |

**References:**

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 111W



Christina M. Miracle  
Manager of Regulatory Compliance





Document No.; DC- 006

Rev. 3

DoC Release Date. *MAY 23, 2016*

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**Revision History:**

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration. Previously Form #0347.15.                                                                                                                                                                                                                                                                                                                                                                                                   |
| 1        | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added Norm-O-Temp Stand with IV Pole (118) and Low Profile Pole (119) to product list. Deleted IEC 60601-2:2007 from Applied Standards List. Updated standards IEC 60601-1-6:2007 to IEC 60601-1-6:2010, IEC 60601-1-2:2004 to IEC 60601-1-2:2007 and ISTA 1D:2001 to ISTA 1C:2001. Updated standard ISO 14971:2007 to ISO 14971:2012. |
| 2        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement.                                                                             |
| 3        | Updated to current template. Added 27; Reusable Hose Extension (P/N 91831) to product list. Updated list of applied standards.                                                                                                                                                                                                                                                                                                                   |



|                                                                                                                |                              |               |
|----------------------------------------------------------------------------------------------------------------|------------------------------|---------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.; <b>DC- 008</b> | Rev. <b>4</b> |
|                                                                                                                | DoC Release Date. 8/3/16     | Page 1 of 4   |

## **DECLARATION OF CONFORMITY**

**Manufacturer:**

**Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
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**EC Representative:**

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Esdoornlaan 13  
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**Warehouse:**

**7100 Dixie Highway  
Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System also complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product Name                 | Description                               | Model Number | CSZ Part # | First date of CE-marking |
|------------------------------|-------------------------------------------|--------------|------------|--------------------------|
| Maxi-Therm                   | (12" x 18") Pad                           | 273          | 50232      | 1998-01                  |
| Maxi-Therm                   | (12" x 18") Pad                           | 273          | 82273      | 1998-01                  |
| Maxi-Therm                   | (22" x 30") Pad                           | 274          | 50231      | 1998-01                  |
| Maxi-Therm                   | (22" x 30") Pad                           | 274          | 82274      | 1998-01                  |
| Maxi-Therm                   | (24" x 60") Pad                           | 276          | 50230      | 1998-01                  |
| Maxi-Therm                   | (24" x 60") Pad                           | 276          | 82276      | 1998-01                  |
| Maxi-Therm Lite Patient Vest | (25" x 53") Patient Vest                  | 800          | 82800      | 2004-07                  |
| Maxi-Therm Lite Patient Vest | (25" x 53") Patient Vest – Large Kool Kit | 801          | 82801      | 2013-05                  |
| Maxi-Therm Lite Pad          | (4" x 25") Pad                            | 870          | 82170      | 1998-01                  |
| Maxi-Therm Lite Pad          | (4" x 25") Pad                            | 870          | 82870      | 1998-01                  |
| Maxi-Therm Lite Pad          | (22" x 17.25") Pad                        | 871          | 82171      | 1998-01                  |
| Maxi-Therm Lite Pad          | (22" x 17.25") Pad                        | 871          | 82871      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 19") Pad                           | 872          | 82172      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 19") Pad                           | 872          | 82872      | 1998-01                  |
| Maxi-Therm Lite Pad          | (12.5" x 18") Pad                         | 873          | 82173      | 1998-01                  |
| Maxi-Therm Lite Pad          | (12.5" x 18") Pad                         | 873          | 82873      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 33") Pad                           | 874          | 82174      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 33") Pad                           | 874          | 82874      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 33") Kool Kit Pad                  | 875          | 82103      | 2007-08                  |
| Maxi-Therm Lite Pad          | (25" x 64") Pad                           | 876          | 82176      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 64") Pad                           | 876          | 82876      | 1998-01                  |
| Maxi-Therm Lite Pad          | (25" x 64") Kool Kit Pad                  | 879          | 82179      | 2013-05                  |
| Connection Hose              | Reusable Converting Connecting Hose       | 287          | 91825      | 1998-01                  |

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Template # 0622.10



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| <br><b>A GENTHERM COMPANY</b> | Document No.; <b>DC- 008</b>    | Rev. <b>4</b> |
|                                                                                                                | DoC Release Date. <b>8/3/16</b> | Page 2 of 4   |

| Product Name    | Description                         | Model Number | CSZ Part # | First date of CE-marking |
|-----------------|-------------------------------------|--------------|------------|--------------------------|
| Connection Hose | Reusable Converting Connecting Hose | 287-18       | 91826      | 1998-01                  |
| Connection Hose | Reusable Converting Connecting Hose | 287-27       | 91831      | 1998-01                  |

  
 Steven J. Berke  
 President

  
 Christina M. Miracle  
 Manager of Regulatory Compliance



|                                                                                                                |                          |             |
|----------------------------------------------------------------------------------------------------------------|--------------------------|-------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.; DC- 008    | Rev. 4      |
|                                                                                                                | DoC Release Date. 8/3/16 | Page 3 of 4 |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Medical devices- Quality Management Systems - Requirements for Regulatory Purposes- Technical Corrigendum 1                                                                                                    |
| EN ISO 10993-1:2009        | Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process                                                                                                      |
| EN ISO 14971:2012          | Medical Devices- Application of risk management to medical devices                                                                                                                                             |
| EN 60601-1-6:2010          | Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability                                                                      |
| EN 60601-2-35:2009         | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| ISTA 1C:2014               | International Shipping Standards – Non-Simulation Integrity Performance Test Procedure                                                                                                                         |
| EN 1041:2008               | Information supplied by the manufacturer of medical devices                                                                                                                                                    |
| EN 980: 2008               | Symbols for use in the labelling of medical devices                                                                                                                                                            |
| EN 60601-1:2005/ A1: 2012  | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                                                         |

**References:**

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF- 870  
CETF- 273

  
 Christina M. Miracle  
 Manager of Regulatory Compliance



|                                                                                                                |                              |               |
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| <br><b>A GENTHERM COMPANY</b> | Document No.; <b>DC- 008</b> | Rev. <b>4</b> |
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### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1        | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Simplified date of Standard ISO 13485:2003. Deleted Titles from the CETF Tech Files on page 2. Updated standard ISO 14971:2007 to ISO 14971:2012. Added model 600 and 601.                                                                                                                                                                                                       |
| 2        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. Updated to include Cat#287, #287-18, and #287-27 extension hoses, Updated to include Manager of Regulatory Compliance |
| 3        | Corrected width for Cat #871 pad. Added part numbers for Maxi-Therm Lite Pads with the self-sealing connectors. Modified description of Connecting Hoses. Corrected part number for Cat #287-27. Updated ISTA to current standard. Updated title and descriptions of standards. Replaced ISO 15223 with EN 980 standard. Updated to current template. Removed Cat #600 and #601. Updated company name. Added standard EN 60601-1: 2005/ A1: 2012.                                          |
| 4        | Updated to new Gentherm Logo. Updated template to 0622.10.                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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| <br><b>A GENTHERM COMPANY</b> | Document No.; DC-009      | Rev. 5      |
|                                                                                                                | DoC Release Date. 3-20-17 | Page 1 of 3 |

## **DECLARATION OF CONFORMITY**

**Manufacturer:**

**Cincinnati Sub-Zero Products, LLC  
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**CSZ Medical Warehouse:**

**7100 Dixie Highway  
Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name      | Description                                              | Model number | CSZ Part # | First date of CE-marking |
|-------------------|----------------------------------------------------------|--------------|------------|--------------------------|
| Plastipad Blanket | Reusable, Hyper/Hypothermia Blanket Infant (12" x 18")   | 193CPC       | 82192      | 1998-01                  |
| PlastiPad Blanket | Reusable Hyper/Hypothermia Blanket Adult (24" x 60")     | 196CPC       | 82184      | 2014-12                  |
| PlastiPad Blanket | Reusable Hyper/Hypothermia Blanket Pediatric (22" x 30") | 194CPC       | 50111      | 2014-12                  |
| Plastipad Blanket | Reusable, Hyper/Hypothermia Blanket Adult (20" x 60")    | 195N         | 50103      | 1998-01                  |
| PlastiPad Blanket | Reusable, Hyper/Hypothermia Blanket Infant (12" x 18")   | 193          | 82193      | 1998-01                  |
| PlastiPad Blanket | Reusable Hyper/Hypothermia Blanket Pediatric (22" x 30") | 194          | 82194      | 1998-01                  |
| PlastiPad Blanket | Reusable Hyper/Hypothermia Blanket Adult (24" x 60")     | 196          | 82196      | 1998-01                  |

  
Steven J. Berke  
President

  
Christina Miracle  
Manager of Regulatory Compliance

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| <br><b>A GENTHERM COMPANY</b> | Document No.; DC-009      | Rev. 5      |
|                                                                                                                | DoC Release Date. 3-20-17 | Page 2 of 3 |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                             |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Quality Management Systems - Requirements for Regulatory Purposes                                                                                                                                               |
| ISO 10993-1:2009           | Biological Evaluation of Medical Devices – Part1: Evaluation and Testing Within a Risk Management Process                                                                                                       |
| EN ISO 14971:2012          | Medical Devices-Application of Risk Management to Medical Devices                                                                                                                                               |
| IEC 60601-1-6:2010         | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.                                                                      |
| IEC 60601-2-35:2009        | Medical Electrical Equipment – Part 2-35: Particular Requirements for the Basic Safety and Essential Performance of Heating Devices Using Blankets, Pads, or Mattresses and Intended for Heating in Medical Use |
| ISTA 1C:2014               | International Shipping Standards – Non-Simulating Integrity Performance Test Procedure                                                                                                                          |
| EN 980:2008                | Symbols for use in the labelling of medical devices                                                                                                                                                             |
| EN 1041:2008               | Information Supplied by the Manufacturer of Medical Devices                                                                                                                                                     |

**References:**

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF-193



**Christina Miracle**  
**Manager of Regulatory Compliance**



|                                                                                   |                           |             |
|-----------------------------------------------------------------------------------|---------------------------|-------------|
|  | Document No.; DC-009      | Rev. 5      |
|                                                                                   | DoC Release Date. 3-20-17 | Page 3 of 3 |

### **Revision History:**

| <b>Rev. No.</b> | <b>Revision Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Orig.</b>    | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>1</b>        | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added 9' Reusable Extension Hose (186) to product list. Deleted part number # 50111 (194CPC). Updated standard ISO 14971:2007 to ISO 14971:2012. Simplified ISO 13485:2003 date.                                                                                                                                                                                                                         |
| <b>2</b>        | Updated DoC form revised template from 0622.6 to 0622.7 which added the RoHS compliance statement; Updated reference to BS EN ISO 14971:2012 by adding the BS EN, Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation, Updated reference from BS EN 980:2008 to ISO 15223-1:2012, Updated reference to BS EN 1041:2008 by adding AM1:2013, Updated to remove part numbers that have been determined non-RoHS compliant, Updated to include Manager of Regulatory Compliance |
| <b>3</b>        | Updated DoC to include part number #50111 (Cat#194CPC) and #82184 (Cat#196CPC), Updated to include Director of Quality & Regulatory Compliance                                                                                                                                                                                                                                                                                                                                                                     |
| <b>4</b>        | Removed IEC and BS from standards. Updated the Manager of Regulatory Compliance.                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>5</b>        | Added Cat 193, 194, and 196.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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Template # 0622.10

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Document No.; DC- 013

Rev. 3

DoC Release Date. *May 23, 2016*

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## DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
Cincinnati, Ohio 45241-1528

EC Representative:

CEpartner4U B.V.  
Esdoornlaan 13  
3951 DB Maarn  
The Netherlands

Warehouse:

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name             | Description                              | Model number | CSZ Part # | First date of CE-marking |
|--------------------------|------------------------------------------|--------------|------------|--------------------------|
| Electri-Cool II 230/240V | Localized Cold Therapy System            | 767          | 86194      | 2004-01                  |
| Dual-Matic               | Flow Rate and Temperature Tester         | TF-100       | 86173      | 2005-09                  |
| Hose Assembly, 6 Ft.     | Hose Assembly, 6 Ft. Insulated           | 757-H1E      | 71600      | 2015-12                  |
| Hose 8 Ft. Dual Pad      | Hose Assembly, 6 Ft. Insulated           | 757-H8D      | 79723      | 2015-12                  |
| Hose 12 in. Dual Pad     | Assembly, Hose 12 in. insulated Dual pad | 757-H1D      | 79701      | 2015-12                  |
| Hose 24 in. Dual Pad     | Assembly, Hose 24 in. Insulated Dual pad | 757-H2D      | 79703      | 2015-12                  |

  
Steven J. Berke  
President / CEO

  
Christina M. Miracle  
Manager of Regulatory Compliance

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Template # 0622.10

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| <br><b>A GENTHERM COMPANY</b> | Document No.: DC- 013                 | Rev. 3      |
|                                                                                                                | DoC Release Date. <i>May 23, 2014</i> | Page 2 of 3 |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                               |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Quality management systems - Requirements regulatory purposes                                                                                     |
| EN ISO 14971:2012          | Medical Devices- Application of risk management to medical devices                                                                                |
| EN 60601-1-6:2010          | Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability                   |
| IEC 60601-1:2005: A1: 2012 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                            |
| EN 60601-1-2:2007          | Medical electrical equipment- Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility requirements and tests |
| ISTA 1C:2001               | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                            |
| ISO 15223-1:2012           | Symbols for use in the labeling of medical devices                                                                                                |
| ISO 980:2008               | Symbols for use in the labeling of medical devices                                                                                                |
| BS EN 1041:2008, AM1:2013  | Information supplied by the manufacturer of medical devices                                                                                       |

**References:**

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 767



Christina M. Miracle  
Manager of Regulatory Compliance



|                                                                                                                |                                       |             |
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| <br><b>A GENTHERM COMPANY</b> | Document No.; DC- 013                 | Rev. 3      |
|                                                                                                                | DoC Release Date. <i>MAY 23, 2016</i> | Page 3 of 3 |

### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                               |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration                                                                                                                                                                                                                                                                                                                                                                |
| 1        | Updated DoC form revised template from 0622.3 to 0622.6. Added First Date of CE Marking column and dates. Added IEC 60601-1:1988, AM1:1991, AM2:1995 to Applied Standard list. Corrected IEC 60601-1-1:2005 to IEC 60601-1:2005 and IEC 60601-1-6:2007 to IEC 60601-1-6: 2010. Simplified the date for standard ISO 13485:2003. Updated standard ISO 14971:2007 to ISO 14971:2012. |
| 2        | Updated DoC form revised template from 0622.6 to 0622.7. Removed standard MEDDEV 2.7.1:2009. Replaced BS EN 980:2008 with ISO 15223:2012. Added AM1:2013 to BS EN 1041:2008.                                                                                                                                                                                                       |
| 3        | Updated to current template. Added Hose Assembly, 6 Ft. (P/N 71600) and Hose 8 Ft., Dual Pad (P/N 79723) to product list. Updated list of applied standards.                                                                                                                                                                                                                       |



|                                                                                                                |                          |             |
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| <br><b>A GENTHERM COMPANY</b> | Document No.; DC- 014    | Rev. 4      |
|                                                                                                                | DoC Release Date. 8/3/16 | Page 1 of 3 |

## DECLARATION OF CONFORMITY

**Manufacturer:**  
**Cincinnati Sub-Zero Products, LLC**  
**12011 Mosteller Road**  
**Cincinnati, Ohio 45241-1528**

**EC Representative:**  
**CEpartner4U B.V.**  
**Esdoornlaan 13**  
**3951 DB Maarn**  
**The Netherlands**

**Warehouse:**  
**7100 Dixie Highway**  
**Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System also complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product Name     | Description                           | Model Number | CSZ Part # | First date of CE-marking |
|------------------|---------------------------------------|--------------|------------|--------------------------|
| Cold Therapy Pad | 5" x 10" Sterile                      | 510-US       | 50625      | 2007-10                  |
| Cold Therapy Pad | 5" x 10" Sterile with Straps          | 510-USS      | 50633      | 2007-10                  |
| Cold Therapy Pad | 5" x 10" Non-sterile                  | 510-NS       | 50733      | 2005-12                  |
| Cold Therapy Pad | 8" x 14" Sterile with Straps          | 814-USS      | 50634      | 2007-10                  |
| Cold Therapy Pad | 8" x 14" Non-sterile                  | 814-NS       | 50734      | 2005-12                  |
| Cold Therapy Pad | 8" x 14" Back Wrap                    | 814-IMB      | 50651      | 2005-12                  |
| Cold Therapy Pad | Universal Knee/Shoulder – Sterile     | CT-99        | 50137      | 2007-10                  |
| Cold Therapy Pad | Universal Knee/Shoulder – Non-sterile | CT-99NS      | 50737      | 2005-12                  |
| Cold Therapy Pad | 11" x 12" Sterile                     | 1112-US      | 50628      | 2007-10                  |
| Cold Therapy Pad | 11" x 12" Sterile with Straps         | 1112-USS     | 50635      | 2007-10                  |
| Cold Therapy Pad | 11" x 12" Non-sterile                 | 1112-NS      | 50735      | 2005-12                  |
| Cold Therapy Pad | 12" x 15" Sterile                     | 1215-US      | 50629      | 2007-10                  |
| Cold Therapy Pad | Head Wrap                             | 600          | 82600      | 2004-09                  |
| Cold Therapy Pad | Head Wrap – Large Kool Kit            | 601          | 82601      | 2013-05                  |

  
**Steven J. Berke**  
**President**

  
**Christina M. Miracle**  
**Manager of Regulatory Compliance**

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|                                                                                                                | DoC Release Date. 8/3/16     | Page 2 of 3   |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                          |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Quality management systems - Requirements for regulatory purposes                                                                                                            |
| EN ISO 10993-1:2009        | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.                                                                  |
| EN ISO 10993-7:2008        | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals                                                                                    |
| EN ISO 11135-1:2007        | Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |
| EN ISO 14971:2012          | Medical Devices- Application of risk management to medical devices                                                                                                           |
| EN 60601-1-6:2010          | Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability                                              |
| ISTA 1C:2001               | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                       |
| EN 1041:2008               | Information supplied by the manufacturer of medical devices                                                                                                                  |
| EN ISO 11607-1:2009        | Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems                                     |
| EN ISO 11607-2:2006        | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes                                            |
| EN 60601-1:2005/ A1: 2012  | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                       |
| EN 980: 2008               | Symbols for use in the labelling of medical devices                                                                                                                          |

**References:**

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF- CT99



Christina M. Miracle  
Manager of Regulatory Compliance

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|                                                                                                                | DoC Release Date. 8/3/16     | Page 3 of 3   |

### **Revision History:**

| <b>Rev. No.</b> | <b>Revision Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.           | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1               | Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Deleted Philips Pads and Kits (82130, 82131, 82132, 82133, 82501, 82502 and 82503. Simplified the date of ISO 13485:2003 standard. Deleted standard IEC 80601-2-35:2009 from the Applied Standards list. Deleted CETF References to Philips pads. Updated standard ISO 14971:2007 to ISO 14971:2012. Deleted reference to CETF-900. Removed models 600 and 601. |
| 2               | Removed Cat #814-US, added IEC 60601-1:2005. Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement.                                                         |
| 3               | Updated template. Added Cat #600 and #601. Updated standards to be harmonized. Added EN 980 and removed ISO 15223 standard. Updated company name.                                                                                                                                                                                                                                                                                                                         |
| 4               | Updated to new Gentherm logo. Updated template to 0622.10.                                                                                                                                                                                                                                                                                                                                                                                                                |

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Document No.: DC- 016

Rev. 7

DoC Release Date. *May 23, 2016*

Page 1 of 3

## DECLARATION OF CONFORMITY

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Warehouse:

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name                         | Description                                      | Model number | CSZ Part # | First date of CE-marking |
|--------------------------------------|--------------------------------------------------|--------------|------------|--------------------------|
| 230V Blanketrol III                  | Hyper/Hypothermia System                         | 233          | 86207      | 2006-06                  |
| 230V Blanketrol III<br>(233BSI-230V) | Hyper/Hypothermia System -<br>British Power Cord | 233          | 86203      | 2013-09                  |
| 230V Blanketrol III<br>(233EL-230V)  | Hyper/Hypothermia System -<br>English Labeling   | 233          | 86204      | 2013-09                  |
| 230V Blanketrol II                   | Hyper/Hypothermia System                         | 222S         | 86265      | 2012-12                  |
| 9' Reusable Hose                     | 9' Reusable Connecting Hose                      | 286          | 91824      | 1998-01                  |
| 27' Reusable Hose<br>Extension       | Hose extension Reusable 287-<br>27 27'           | 287-27       | 91831      | 2015-11                  |
| 18' Reusable Hose                    | 18' Reusable Connecting Hose                     | 286-18       | 91840      | 1998-01                  |
| 27' Reusable Hose                    | 27' Reusable Connecting Hose                     | 286-27       | 91841      | 1998-01                  |
| Bill Data Export<br>Software         | Bill USB Software                                | USB-<br>127  | 86127      | 2012-07                  |
| Tri-Matic                            | Temp., Flow and Resistance<br>Tester             | TFRW         | 86171      | 1998-01                  |
| Hose Assembly<br>TM-6                | Hose Assembly CSZ/Trimatic<br>(TM-6)             | TM6          | 91802      | 2015-11                  |

  
Steven J. Berke  
President / CEO

  
Christina M. Miracle  
Manager of Regulatory Compliance

### Applied standards in full or in part:

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| <u>Standard No.</u>                  | <u>Title</u>                                                                                                                                                                                                   |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003                       | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                            |
| BS EN ISO 14971:2012                 | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                             |
| IEC 60601-1-6:2010                   | Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability                                                                                |
| IEC 60601-1:2005                     | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                                                         |
| IEC 60601-2-35:2009                  | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| IEC 60601-2-35:1996                  | Medical electrical equipment – Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use                                                            |
| IEC 60601-1-2:2004                   | Medical electrical equipment- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility requirements and tests                                                             |
| IEC 60601-1-2:2007                   | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests                         |
| IEC 60601-1:1988, AM1:1991, AM2:1995 | Medical electrical equipment- Part 1 - General requirements for safety                                                                                                                                         |
| ASTM-F2196-02:2002                   | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices                                                                                                            |
| ISTA 1D:2001                         | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                                         |
| ISO 15223-1:2012                     | Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied                                                                                                      |
| BS EN 1041:2008, AM1:2013            | Information supplied by the manufacturer of medical devices                                                                                                                                                    |

**References:**

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 233

Christina M. Miracle  
Manager of Regulatory Compliance



|                                                                                                                |                                       |             |
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| <br><b>A GENTHERM COMPANY</b> | Document No.: <b>DC- 016</b>          | Rev. 7      |
|                                                                                                                | DoC Release Date. <i>MAY 23, 2016</i> | Page 3 of 3 |

### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1        | Updated to comply with IEC 60601-1: 2005, IEC 80601-2-35: 2009                                                                                                                                                                                                                                                                                                                                                                                                  |
| 2        | Updated to new DoC template form #0622.4. Added Part No. 86265.                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3        | Updated DoC from revised template from 0622.4 to 0622.6. Added First Date of CE Marking column and dates. Added Tri-Matic Tester to the product list. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010, ISTA 1C: 2001 to ISTA 1D:2001 and ISO14971:2007 to ISO14971:2012 in the Applied Standards list.                                                                                                                                                         |
| 4        | Updated to add 230V British Power Cord Blanketrol III, Model 233 (233BSI-230V).                                                                                                                                                                                                                                                                                                                                                                                 |
| 5        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. Removed TriMatic from DoC (P/N 86171). Added Blanketrol III 233EL-230V to DoC (P/N 86204). |
| 6        | Added Tri-Matic (P/N: 86171) to the DoC.                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 7        | Updated to current template. Added 27' Reusable Hose Extension (P/N 91831) and Hose Assembly TM-6 (P/N 91802) to product list. Updated standards list to harmonized European standards where applicable.                                                                                                                                                                                                                                                        |





Document No.: DC-017

Rev. 6

DoC Release Date. 7/21/2016

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## DECLARATION OF CONFORMITY

**Manufacturer:**

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3951 DB Maarn  
The Netherlands

**CSZ Medical Warehouse:**

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System also complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product Name     | Description                                                                                  | Model Number | CSZ Part # | First date of CE-marking |
|------------------|----------------------------------------------------------------------------------------------|--------------|------------|--------------------------|
| Kool Kit         | Patient Vest, Head Wrap & 875 Blanket                                                        | 900          | 82900      | 2007-08                  |
| Head Wrap Kit    | Head Wrap & 875 Blanket                                                                      | 910          | 82910      | 2008-01                  |
| Patient Vest Kit | Patient Vest & 875 Blanket                                                                   | 920          | 82920      | 2008-01                  |
| Large Kool Kit   | Patient Vest, Head Wrap & 879 Blanket                                                        | 930          | 82930      | 2013-05                  |
| Kool Kit Neonate | 875 Blanket, Temperature Probe (Manufactured by Measurement Specialties), mittens, and socks | 950          | 82950      | 2011-06                  |



Steven J. Berke  
President



Christina Miracle  
Manager of Regulatory Compliance

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DoC Release Date. 7/21/2016

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**Applied standards in full or in part:**

| Standard           | Title                                                                                                                                                                                                          |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003     | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                            |
| ISO 10993-1:2009   | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.                                                                                                    |
| EN ISO 14971:2012  | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                             |
| EN 60601-1-6:2010  | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.                                                                     |
| EN 60601-2-35:2009 | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| ISTA 1C:2001       | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                                         |
| EN 980:2008        | Symbols for use in the labelling of medical devices                                                                                                                                                            |
| EN 1041:2008       | Information supplied by the manufacturer of medical devices                                                                                                                                                    |

**References:**

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF- 900

Christina Miracle  
Manager of Regulatory Compliance



|                                                                                                                |                             |             |
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| <br><b>A GENTHERM COMPANY</b> | Document No.: DC-017        | Rev. 6      |
|                                                                                                                | DoC Release Date. 7/21/2016 | Page 3 of 3 |

### **Revision History:**

| <b>Rev. No.</b> | <b>Revision Description</b>                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1               | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2               | Revised to include the Bariatric Kool Kit, Model 930                                                                                                                                                                                                                                                                                                                                                                |
| 3               | Bariatric Kool-Kit became Large Kool-Kit.                                                                                                                                                                                                                                                                                                                                                                           |
| 4               | Updated DoC from revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Delete ISO 15223-2:2010 standard from the Applied Standards List. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010 and ISO 14971:2007 to ISO14971:2012 in the Applied Standards list. Added IEC 80601-2-35:2009.                                                                                          |
| 5               | Removed references to InnerCool Pads and Kits. Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. |
| 6               | Updated Manager of Regulatory compliance. Removed BS and IEC from standards.                                                                                                                                                                                                                                                                                                                                        |



|                                                                                                                |                                       |             |
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| <br><b>A GENTHERM COMPANY</b> | Document No.; <b>DC-018</b>           | Rev. 3      |
|                                                                                                                | DoC Release Date. <i>May 23, 2014</i> | Page 1 of 3 |

## DECLARATION OF CONFORMITY

Manufacturer:

**Cincinnati Sub-Zero Products, LLC**  
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**7100 Dixie Highway**  
**Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name                                          | Description                                 | Model number | CSZ Part # | First date of CE-marking |
|-------------------------------------------------------|---------------------------------------------|--------------|------------|--------------------------|
| Hemotherm                                             | Dual Reservoir Cooler/Heater System         | 400CE        | 86023      | 2009-02                  |
| Hemotherm Remote Control                              | Wired, Remotely – Located Controller        | 414CE        | 93816      | 2009-11                  |
| Hemotherm Flow Indicator with Shut-off Valve Assembly | Flow Indicator with Shut-off Valve Assembly | 420          | 93808      | 1998-01                  |
| Connecting Hose                                       | 9' Reusable Connecting Hose                 | 286          | 91824      | 1998-01                  |
| Connecting Hose                                       | 18' Reusable Connecting Hose                | 286-18       | 91840      | 1998-01                  |
| Connecting Hose                                       | 27' Reusable Connecting Hose                | 286-27       | 91841      | 1998-01                  |

  
**Steven J. Berke**  
**President / CEO**

  
**Christina M. Miracle**  
**Manager of Regulatory Compliance**



|                                                                                                                |                                       |             |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.; <b>DC-018</b>           | Rev. 3      |
|                                                                                                                | DoC Release Date. <i>May 23, 2016</i> | Page 2 of 3 |

**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN ISO 14971:2012          | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                             |
| ISO 13485:2003             | Medical Devices — Quality management systems — Requirements for regulatory purposes                                                                                                                            |
| IEC 60601-1:2005; A1: 2012 | Medical electrical equipment- Part 1: General requirements for basic safety and essential performance                                                                                                          |
| EN 60601-1-2:2007          | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests                         |
| EN 60601-1-6:2010          | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability                                                                      |
| ASTM-F2196-02:2002         | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices                                                                                                            |
| EN 80601-2-35:2009         | Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| ISTA 1D:2001               | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                                         |
| ISO 15223-1:2012           | Symbols for use in the labeling of medical devices                                                                                                                                                             |
| EN 980:2008                | Symbols for use in the labeling of medical devices                                                                                                                                                             |
| EN 1041:2008,              | Information supplied by the manufacturer of medical devices                                                                                                                                                    |

**References:**

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 400CE



Christina M. Miracle  
Manager of Regulatory Compliance





Document No.; DC-018

Rev. 3

DoC Release Date. MAY 23, 2016

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### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                   |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration, previously on Form 0347.15.                                                                                                                                                                                                                                                                                                       |
| 1        | Updated DoC from revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added Universal Mounting Clamp and Flow Indicator with Shut-off Valve Assembly to product list. Updated ISO 14971:2007 to ISO14971:2012 in the Applied Standards list. Added connecting hoses 91824, 91840, 91841 and 89186 to Product List. |
| 2        | Updated DoC form revised template from 0622.6 to 0622.7. Removed standard MEDDEV 2.7.1:2009. Replaced BS EN 980:2008 with ISO 15223:2012. Added AM1:2013 to BS EN 1041:2008.                                                                                                                                                                           |
| 3        | Removed Universal Mounting Clamp (P/N 91811) from product list. Updated to current Template. Updated list of Applied Standards.                                                                                                                                                                                                                        |





Document No.: DC-019

Rev. 3

DoC Release Date. 7/21/2016

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## DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC  
12011 Mosteller Road  
Cincinnati, Ohio 45241

EC Representative:

CEpartner4U B.V.  
Esdoornlaan 13  
3951 DB Maarn  
The Netherlands

CSZ Medical Warehouse:

7100 Dixie Highway  
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name | Description | Model number | CSZ Part # | First date of CE-marking |
|--------------|-------------|--------------|------------|--------------------------|
| Gelli-Roll   | Infant      | 193P         | 82197      | 2007-05                  |
| Gelli-Roll   | Pediatric   | 194P         | 82198      | 2007-05                  |
| Gelli-Roll   | Adult       | 195P         | 82199      | 2007-05                  |

  
Steven J. Berke  
President

  
Christina Miracle  
Manager of Regulatory Compliance

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Template # 0622.10

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**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                                              |
| ISO 10993-1:2009           | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)                                                                                  |
| EN ISO 14971:2012          | Medical Devices – Application to Risk Management to Medical Devices                                                                                                                                            |
| EN 60601-1-6:2010          | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.                                                                     |
| EN 80601-2-35:2009         | Medical Electrical Equipment – Part 2-35: Particular Requirements for the Basic Safety and Essential Performance of Heating Devices Using Blankets, Pads or Mattresses and Intended for Heating in Medical Use |
| ISTA 1C:2001               | International Shipping Standards – Non-Simulating Integrity Performance Test Procedure                                                                                                                         |
| EN 980:2008                | Symbols for use in the labelling of medical devices                                                                                                                                                            |
| EN 1041:2008               | Information Supplied by the Manufacturer of Medical Devices                                                                                                                                                    |

**References:**

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF-193P

Christina Miracle  
Manager of Regulatory Compliance



|                                                                                   |                             |             |
|-----------------------------------------------------------------------------------|-----------------------------|-------------|
|  | Document No.: DC-019        | Rev. 3      |
| A GENTHERM COMPANY                                                                | DoC Release Date. 7/21/2016 | Page 3 of 3 |

### **Revision History:**

| Rev.<br>No. | Revision Description                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.       | Initial declaration                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1           | Updated DoC form revised template from 0622.5 to 0622.6, Added First Date of CE Marking column and dates.. Simplified the ISO 13485:2003 date, Updated standard ISO 14971:2007 to ISO 14971:2012                                                                                                                                                                                                                             |
| 2           | Updated reference to BS EN ISO 14971:2012 by adding the BS EN, Removed reference to MEDDEV 2.7.1:2009, Guidelines on Medical Devices -- Clinical Evaluation, Updated reference from BS EN 980:2008 to ISO 15223-1:2012, Updated reference to BS EN 1041:2008 by adding AM1:2013, Updated DoC template from 0.622.6 to 0.622.7 which added the RoHS compliance statement, Updated to include Manager of Regulatory Compliance |
| 3           | Updated Manager of Regulatory compliance. Removed BS and IEC from standards.                                                                                                                                                                                                                                                                                                                                                 |



|                                                                                                                |                                       |             |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.; DC-020                  | Rev. 4      |
|                                                                                                                | DoC Release Date. <i>May 23, 2016</i> | Page 1 of 3 |

## **DECLARATION OF CONFORMITY**

Manufacturer:

**Cincinnati Sub-Zero Products, LLC**  
**12011 Mosteller Road**  
**Cincinnati, Ohio 45241-1528**

EC Representative:

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**The Netherlands**

Warehouse:

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**Fairfield, Ohio 45014**

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

| Product name              | Description                 | Model number | CSZ Part # | First date of CE-marking |
|---------------------------|-----------------------------|--------------|------------|--------------------------|
| 230V InnerCool STx System | Hyper/Hypothermia System    | 25-01        | 86001      | 2008-03                  |
| 9' Reusable Hose          | 9' Reusable Connecting Hose | 26-01        | 91844      | 2008-03                  |

  
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 Manager of Regulatory Compliance



Document No.: **DC-020**

Rev. 4

DoC Release Date:

*May 23, 2016*

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**Applied standards in full or in part:**

| <b><u>Standard No.</u></b> | <b><u>Title</u></b>                                                                                                                                                                                |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 13485:2003             | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes                                                                                                                |
| EN ISO 14971:2012          | Medical Devices- Application of Risk Management to Medical Devices                                                                                                                                 |
| EN 60601-1-6:2010          | Medical Electrical Equipment – General requirements for basic safety and essential performance – Collateral standard: Usability                                                                    |
| IEC EN 60601-1-2-:2007     | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests             |
| EN 80601-2-35: 2009        | Medical electrical equipment: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use |
| IEC 60601-1:2005; A1: 2012 | Medical electrical equipment – Part 1: general requirements for basic safety and essential performance.                                                                                            |
| ASTM-F2196-02:2002         | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices                                                                                                |
| ISTA 1D:2001               | International Shipping Standards - Non-Simulating Integrity Performance Test Procedure                                                                                                             |
| EN 980:2008                | Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied                                                                                          |
| ISO 15223-1:2012           | Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied                                                                                          |
| EN 1041:2008,              | Information supplied by the manufacturer of medical devices                                                                                                                                        |

**References:**

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 25-01

Christina M. Miracle

Manager of Regulatory Compliance



|                                                                                                                |                                       |             |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------|
| <br><b>A GENTHERM COMPANY</b> | Document No.: <b>DC-020</b>           | Rev. 4      |
|                                                                                                                | DoC Release Date. <i>MAY 23, 2016</i> | Page 3 of 3 |

### Revision History:

| Rev. No. | Revision Description                                                                                                                                                                                                                                                                                                                                                 |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Orig.    | Initial declaration                                                                                                                                                                                                                                                                                                                                                  |
| 1        | Updated DoC to new template form #0622.4, included labeling changes per Philips Healthcare request.                                                                                                                                                                                                                                                                  |
| 2        | Updated DoC form revised template from 0622.4 to 0622.6. Added First Date of CE Marking column and dates. Corrected IEC 60601-1-6:2007 to IEC 60601-1-6:2010 and IEC 60601-2:2007 to IEC 60601-1-2:2007 in the Applied Standards list. Updated standard ISO 14971:2007 to ISO 14971:2012.                                                                            |
| 3        | Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. |
| 4        | Removed 9' Reusable Connecting Hose (P/N 91844) from product list. Updated to current template. Updated list of Applied standards.                                                                                                                                                                                                                                   |



## Convective Warming System

## WarmAir® &amp; FilteredFlo®

The WarmAir® warming system is a compact, lightweight unit that delivers gently moving warm air using a low velocity blower. All air is filtered through the WarmAir® unit and the FilteredFlo® blankets. With built-in safety monitoring systems, caregivers will be alerted if the temperatures exceed or fall below temperature settings, providing further protection to your patient.

The unique patented design of FilteredFlo® blankets permits the use of a lower velocity blower to supply gently moving, clean air. The filtered air warming method minimizes air currents that may spread contaminants to the patient.

- Helps keep patients comfortable before and after surgery
- Can improve maintenance of warm body temperature during surgery
- Provides patient warmth after surgery
- May help accelerate healing and recovery time



1. Sessler D, Kurz A, Lenhardt R. "Perioperative Normothermia to Reduce the Incidence of Surgical Wound Infection and Shorten Hospitalization." NE Journal of Medicine.1996; 334 (19): 1209-1215.



*Cincinnati Sub-Zero has been managing your patient temperature needs for over 45 years.*



# Convective Warming Systems



## Convective air warming provides the following patient benefits:

- Reduces hypothermia during most surgical procedures
- Designed to keep your patients normothermic
- May help improve patient recovery time, minimizing the length of hospital stays

## WarmAir® warming unit has:

- Reduces air circulating in the room
- Quiet operation
- Four levels of therapy
- Compact and lightweight frame
- High and low temperature alarms





Recent studies have proven that warming patients before, during and after surgery and other specialty procedures can markedly improve clinical outcomes.<sup>1</sup>

### **FilteredFlo® Blankets:**

- Provide therapy before, during and after surgery
- Offer uniform warm air distribution
- Easy to manage and will not “fly away”
- Can be folded back for easy access to your patient



### **CSZ uses Filtered Air Warming as opposed to Forced Air Warming**

The unique patented design of FilteredFlo® blankets permits use of a lower velocity blower to supply gently moving, clean air. The filtered air warming method minimizes air currents that may spread contaminants to your patient.



CSZ FilteredFlo® blankets keep the warm air close to the blanket and close to the patient.



Forced Air method with competitor's blanket

1. Sessler D, Kurz A, Lenhardt R. "Perioperative Normothermia to Reduce the Incidence of Surgical Wound Infection and Shorten Hospitalization." NE Journal of Medicine.1996; 334 (19): 1209-1215.



# WarmAir® & FilteredFlo®

## Convective Warming System

| Ordering Information  |                                                      |                                                                                     |           |
|-----------------------|------------------------------------------------------|-------------------------------------------------------------------------------------|-----------|
| Cat. No.              | Description                                          | Quantity                                                                            |           |
| 135                   | WarmAir®                                             | 110v/115v, 100v, 220v/240v                                                          |           |
| UNV LPS               | Universal Stand                                      | ea.                                                                                 |           |
| FilteredFlo® Blankets |                                                      |                                                                                     |           |
| 243                   | Adult<br>92in x 50in (233.7cm x 127cm)               |    | 10/carton |
| 443                   | Upper Body<br>88in x 30in (223.5cm x 76.2cm)         |    | 10/carton |
| 442                   | Lower Body<br>53in x 40in (134.6cm x 101.6cm)        |    | 10/carton |
| 344                   | Torso<br>43in x 40in (109.2cm x 101.6cm)             |    | 10/carton |
| 244                   | Pediatric<br>56in x 40in (142.2cm x 101.6cm)         |    | 10/carton |
| 246                   | Infant<br>24in x 37in (61cm x 94cm)                  |    | 10/carton |
| 542                   | Sterile Cardiac<br>72in x 50in (182.8cm x 127cm)     |   | 5/carton  |
| 145                   | Warming Tube<br>28in x 66in (71.1cm x 167.6cm)       |  | 25/carton |
| 248                   | Adult Underbody<br>78.5in x 40in (199.4cm x 101.6cm) |  | 10/carton |

### Product Specifications:

#### Dimensions:

8.75" W x 8.75" D x 13.5" H  
(22.2cm x 22.2cm x 34.3cm)

**Weight:** 13.5 lbs. (6.1kg)

#### Filtration:

0.3 microns, High Efficiency

#### Minimum Airflow:

28 cfm (100v, 115v)  
26 cfm (230v)

#### Temperature Settings:

No Heat (ambient temperature)  
32.2°C +4°C/-2°C (90°F +7.2°F/-3.6°F)  
37.8°C +4°C/-2°C (100°F +7.2°F/-3.6°F)  
43.3°C +4°C/-2°C (110°F +7.2°F/-3.6°F)

#### Operating Environment:

16°C - 27°C (60°F - 80.6°F)

#### Maximum Contact Surface Temp:

48°C (118.4°F)

#### Maximum Temperature Setting:

43.3°C + 4.0°C (110°F + 8°F)

#### Safety Alarms:

Audible & Visible alarms for over and under temperature limits

Warming Tube™



Infant Blanket



**CSZ**  
Cincinnati Sub-Zero

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[www.cszmedical.com](http://www.cszmedical.com)

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