# SPARE FILTER for Clinic, SuperVega trolley - connector 11 mm

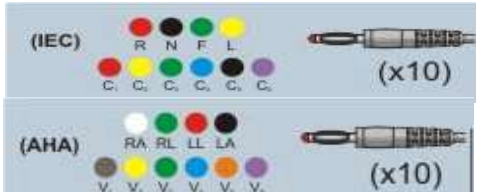
| | |
|---|---|
| **Code:** | **28239** |
| **Category:** | **Filtres** |
| **Unit of sale:** | **1 pc.** |
| **Minimum order:** | **1** |
| **Type:** | **Medical device** |
| **Class:** | **II A** |
| **NSIS:** | **314052** |
| **CND:** | **A0680** |
| **EAN13:** | **8023279282399** |

**Description:**

**Hydrophobic 99% antibacterial filter, spare for the following aspirators:**

**- Clinic**
**- Super Vega on trolley**

Digitally signed by Grabazei Alexandru
Date: 2019.04.14 13:08:05 EEST
Reason: MoldSign Signature
Location: Moldova


***Fukuda Denshi***

| Compatible Brand | OEM P/N | Greatmade No. | Desceiption ( Cable and connector ) | 1-5pcs | 6-19pcs | Above 20pcs |
|---|---|---|---|---|---|---|
| **Fukuda** | FX-101 | EC002A | Fukuda EKG cable , ***IEC***, DB15M> ***Din 3.0*** | | | |
| FCP-7411, FX-7402, | | EC002AD | Fukuda EKG cable , **AHA**, DB15M>**DIN 3.0** | | | |
| FX-7202, FX-2111 | | EC002B | Fukuda EKG cable , ***AHA***, DB15M>***Banana 4.0*** | | | |
| FX-2155, FX-3010, | | EC002BI | Fukuda EKG cable , ***IEC***, DB15M>***Banana 4.0*** | | | |
| F-7102 | | EC002C | Fukuda EKG cable , ***AHA***, DB15M>**Grabber** | | | |
| **Customed** : Custo Card | | EC002CI | Fukuda EKG cable , ***IEC***, DB15M>***Grabber*** | | | |
| **Bosch : 603D /603ER** | | EC002D | Fukuda EKG cable , ***AHA***, DB15M>**Snap** | | | |
| /603S/606 | | EC002DI | Fukuda EKG cable , ***IEC***, DB15M>**Snap** | | | |


**Fukuda ME**

| Compatible Brand | OEM P/N | Greatmade No. | Desceiption ( Cable and connector ) | 1-5pcs | 6-19pcs | Above 20pcs |
|---|---|---|---|---|---|---|
| Fukuda | | EC027A | Fukuda ME KP-500 EKG cable , **IEC**, ***DB15M>DIN 3.0mm , no resistor ,*** | | | |
| KP-500 | | EC027AD | Fukuda ME KP-500 EKG cable , **AHA**, ***DB15M>*** **DIN 3.0mm , no resistor** | | | |
| | | EC027B | Fukuda ME KP-500 EKG cable , **AHA**, ***DB15M>*** ***Banana 4.0*** , **no resistor ,** | | | |
| | | EC027BI | Fukuda ME KP-500 EKG cable ,**IEC**, ***DB15M> Banana 4.0 , no resistor*** | | | |
| | | EC027C | Fukuda ME KP-500 EKG Cable , ***AHA , DB15M>Grabber*** , **no resistor** | | | |
| | | EC027CI | Fukuda ME KP-500 EKG Cable , **IEC**, ***DB15M>Grabber*** ,**no resistor** | | | |
| | | EC027D | Fukuda ME KP-500 EKG Cable , ***AHA , DB15M>Snap ,no resistor*** | | | |
| | | EC027DI | Fukuda ME KP-500 EKG Cable ,IEC, ***DB15M>Snap ,no resistor*** | | | |

# Declaration of Conformity

## According to the Medical Devices Directive 93/42/EEC

| | |
|---|---|
| **Manufacturer's Name :** | **HK Greatmade Tech Limited** |
| **Manufacturer's Address :** | **4th, A building ,PinChuangYuan Science Technology Park ,ShuiDou New Village ,LongHua Town** |
| | **Shenzhen City , Guang Dong Province , China** |
| **Product :** | **ECG cable and Leadwire, class I** |
| **Type Designation/Trademark :** | **ECG cable with leadwires** |

**Product Part No. Of Manufacturer:**
**EC001A,EC001AD,EC001B,EC001C,EC001BI,EC001D,EC001DI,EC025A,EC025AD,EC025B,EC025BI,EC025C,EC025D,EC002AD,EC002A,EC002B,EC002BI,EC002C,EC002D,EC027A,EC027B,EC027C,EC027B,EC027A-R,EC027B-R,EC027C-R,EC027D-R,EC028A,EC008B,EC028D,EC028DI,EC030A,EC003AI,EC003A,EC004,EC004B,EC004C,EC005A,EC005B,EC005C,GE-EC022-SA,GE-EC022-CA,EC026A,EC026B,EC026C,EC029A,EC029B,EC024A/B/C/D,EC033A/B/C/D/E,EC038A/B/C/D/E/F,EC040,MR-EC0331A/B/C/D/AD/BI/BI/DI,EC006A/B/C/D,EC007A,EC007B,EC007C,EC007D/E/F/H/G,EC007A-R,EC007B-R,EC007D-R.EC00C-R,EC015A/B/C/D,EC007I,EC009A,EC009B/C/D/E/F,EC021A/B/C/D/E/F,EC010A,EC010B/C/D/E/F,EC016A/B,EC017A/B,EC011A/B/C/D,EC019A/B/C/D,EC020A/B/C/D/E/F/G/H,EC042A/B/C/D,EC041A/I,EC035A/B/C/D/E/F/G/H,EC043A/B,EC012A/B/C,EC012A/B/C/D-HP,EC012E/F,EC013A/B/C/D/E/F/G,EC018A/B/C/D,EC036A/B,EC037A/B,EC039A/B,EC014A/P ,EC023A/B/C,EC034.**

**Authorized representative established within the EU (if applicable):**

**Company Name:**

**Company Address :**

**Person responsible for making this declaration**

| | |
|---|---|
| **Name, Surname :** | **ZhangHanzhi** |
| **Position/Title :** | **Director , Owner** |

**Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC**

Shenzhen China

Zhang Hanzhi

**(Place)**
**(Company stamp and legal signature)**

**2013.11.01**
**(Date)**

# TECHNICAL FILE

## Vygon Spike 5µm (blue)

281.02

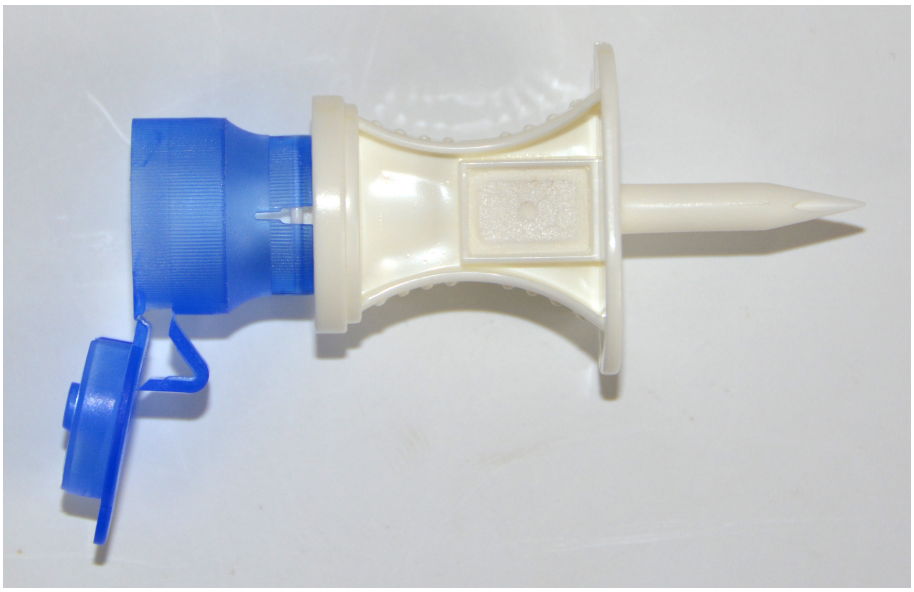
Dated : 04-04-2019

## 1 Administrative information relating to the company

| | | |
|---|---|---|
| 1.1 | **Name** : Vygon SA | |
| 1.2 | **Address :**<br>5 rue Adeline - 95440 Ecouen, France | **Fax :** + 33 (0)1 34 29 19 34<br>**E-mail :** questions@vygon.com<br>**Website :** www.vygon.com |
| 1.3 | **Medical Device vigilance Representative :**<br>Laurent GUILLARDEAU | **Tel :** +33 (0)1 39 92 65 69<br>**Fax :** +33 (0)1 39 92 64 82<br>**E-mail :** quality@vygon.com |

## 2 Information about the device or equipment

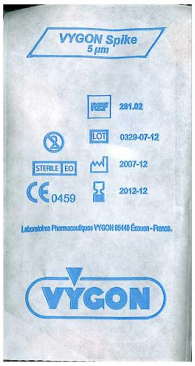
| | |
|---|---|
| 2.1 | |
| 2.2 | **Commercial name :** Vygon Spike 5µm (blue) |
| 2.4 | **Medical Device Class :** Is<br>**Applicable EU Directive :** 93/42/CEE<br>**in accordance with Appendix n° :** VII / V<br>**Notified body N° :** 0482<br>**Medical Device Manufacturer :** RoweMed |
| 2.5 | **Description of the device :**<br>Single use, sterile, needleless device intended for fluid withdrawal, powdered medicine reconstitution and injection.<br>It is recommended for the reconstitution of sterile medicines: the preparation of powdered or lyophilisate solutions, preparation of eye drops, etc, and for repeated withdrawals from the same vial using a syringe.<br><br>Vygon Spike, code 281.02, includes a 0.1µm hydrophobic air-venting fluid filter, and a 5µm solution filter recommended for withdrawing or injecting reconstituted or lyophilisate medicines post preparation.<br>Easy identification by a "Blue" colour..<br><br>Also available:<br>- Vygon Spike, code 281.01, includes a 0.1µm hydrophobic air-venting fluid filter, recommended for handling standard products under aseptic conditions.<br>Easy identification by a "Green" colour.<br><br>- Vygon Spike Chemo code 281.03, includes a 0.1µm hydrophobic air-venting fluid filter, a 5µm solution filter and made from a high chemical resistant polymer (material) designed specifically for handling cytotoxic medicines.<br>Easy identification by a "Red" colour.<br><br>Standard connection adapted to fit all types of syringes<br>Simple and ergonomic handling<br><br>Latex- and PVC-free |



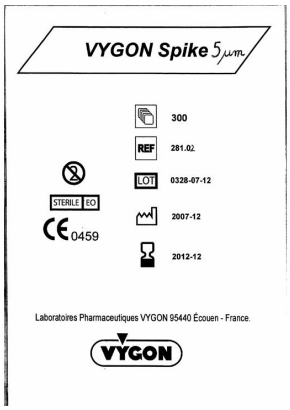
## 2.6 Packaging / Containers

| Code | Single unit packaging | Multi unit packaging | Minimum delivery quantity | Case |
|---|---|---|---|---|
| 281.02 | 1 (Peel-pack) | 300 (Carton box) | 300 (Carton box) | 300 (Carton box) |

### Single unit packaging

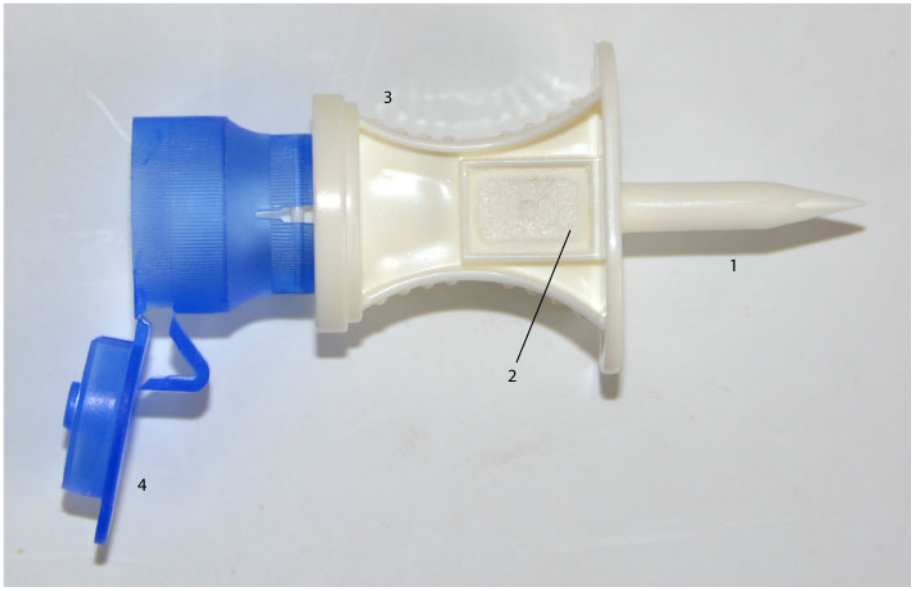



### Box



| | |
|---|---|
| | **Technical features :** |

| Code | Spike | | | |
|---|---|---|---|---|
| | Priming volume ml | Filter porosity µm | Filtering area $cm^2$ | Utilization pressure (maximum) bar |
| 281.02 | 0.16 | 5 | 1.29 | 1 |

| | |
|---|---|
| **2.7** | **Composition of the device and Accessories :** 281.02 |
| |  <br>**For components which are likely to come into contact with the patient and/or administered products, additional points :**<br>Latex-free<br>DEHP-free<br>Does not contain any products of animal or biological origin |
| **2.8** | **Indications :**<br>It is recommended for handling standard products in vials under optimal aseptic conditions. |

## 3 Accessories

## 4 Sterilization process

| | |
|---|---|
| | **Sterile Medical Device :** YES<br>**Sterilization made for the device :** Ethylene oxide |

## 5 Conditions of conservation and storage

| | |
|---|---|
| **5.1** | **Normal conservation and storage conditions :**<br>Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight. |
| **5.2** | |

| | |
|---|---|
| 5.3 | **Duration of product validity :** 60 months |

## 6 Security of use

## 7 Instructions for use

| | |
|---|---|
| 7.1 | |
| 7.2 | |
| 7.3 | |
| 7.4 | |

## 8 Additional information relating to the product

# PLASTIplast

## adhesive fabric tape

**features:**
- made of cotton fabric
- skin colour
- on a roll
- serrated edge
- good air and vapour permeability
- good adhesiveness
- elastic - comfortable for the patient, adjusts to the body shape and guarantees freedom of movement
- can be separated along and across, also without using scissors
- hypoallergenic
- non-sterile

**indication:**
- stabilization, protection and fixation of non-adhesive primary dressings put directly on wounds or injured skin
- stabilization, protection and fixation of drains, cannulas and medical tubes

| ref. | dimensions | packaging unit/box | bulk packaging |
|---|---|---|---|
| SZO12505S | 1.25 cm x 5 m | 24 pcs | 30 boxes |
| SZO25005S | 2.5 cm x 5 m | 12 pcs | 30 boxes |
| SZO50005S | 5 cm x 5 m | 6 pcs | 30 boxes |

# SOFTplast

## adhesive non-woven tape

**features:**
- made of non-woven fabric
- white
- on a roll
- straight edge
- good air and vapour permeability
- good adhesiveness
- elastic - comfortable for the patient, adjusts to the body shape and guarantees freedom of movement
- can be separated along and across, also without using scissors
- hypoallergenic
- non-sterile

**indication:**
- stabilization, protection and fixation of non-adhesive primary dressings put directly on wounds or injured skin
- stabilization, protection and fixation of drains, cannulas and medical tubes

| ref. | dimensions | packaging unit/box | bulk packaging |
|---|---|---|---|
| SNW12505W | 1.25 cm x 5 m | 24 pcs | 30 boxes |
| SNW25005W | 2.5 cm x 5 m | 12 pcs | 30 boxes |
| SNW50005W | 5 cm x 5 m | 6 pcs | 30 boxes |
| SNW12509W | 1.25 cm x 9.14 m | 24 pcs | 30 boxes |
| SNW25009W | 2.5 cm x 9.14 m | 12 pcs | 30 boxes |
| SNW50009W | 5 cm x 9.14 m | 6 pcs | 30 boxes |

# elastopor STERIL D

## non-woven swab with absorbent pad, incision and O-hole, self-adhesive, sterile

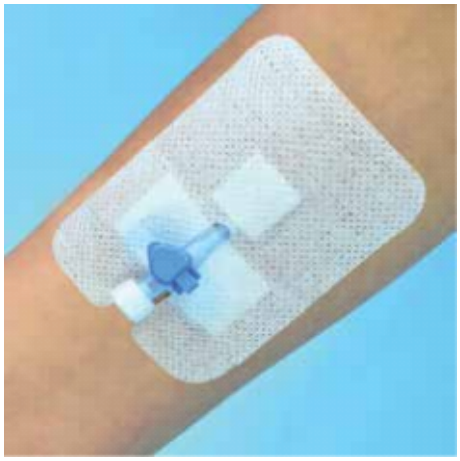
**features:**
- made of hydrophobic non-woven material
- incision and O-hole enabling application around a fixed drain
- covered with hypoallergenic acrylic glue
- micropores in the non-woven material structure provide an adequate rate of moisture vapour permeability so correct gas exchange between the dressing and skin is guaranteed
- centrally situated absorbent pad coated with polyethylene mesh absorbs small amounts of exudates, protects against external factors' influence and does not stick to the wound as well as facilitates removal of the dressing
- elastic - comfortable for the patient, adjusts to the body shape and guarantees freedom of movement
- rounded edges prevent accidental removal of the dressing
- silicone paper backing facilitates precise, painless and efficient application
- hypoallergenic
- sterile

**indication:**
- protection of the site of drain or catheter application
- dressing wounds with small and medium exudate level

| ref. | dimensions | packaging unit/ pouch | intermediate packaging/box | bulk packaging |
|---|---|---|---|---|
| 801031 | 9 cm x 10 cm | 1 pc. | 30 pcs | 24 boxes |
| 801030 | 12 cm x 14 cm | 1 pc. | 25 pcs | 16 boxes |

# elastopor IV

## non-woven IV cannula dressing, self-adhesive, sterile



**features:**
- made of hydrophobic non-woven material
- adhesive
- covered with hypoallergenic acrylic glue
- centrally situated absorbent pad protects the non-woven material from sticking to the injection site
- non-woven lining should be placed under cannula's wings, which prevents it from causing damage to the skin
- rounded edges prevent accidental removal of the dressing
- micropores in the non-woven material structure provide an adequate rate of moisture vapour permeability so correct gas exchange between the dressing and skin is guaranteed
- elastic - adjusts to the body shape and guarantees freedom of movement
- silicone paper backing facilitates precise, painless and efficient application
- hypoallergenic
- sterile

**indication:**
- stabilization, protection and fixation of intravenous cannulas

| ref. | dimensions | packaging unit/ pouch | intermediate packaging/box | bulk packaging |
|---|---|---|---|---|
| 811013 | 6 cm x 8 cm | 1 pc. | 100 pcs | 20 boxes |
| 811023 | 6 cm x 8 cm | 1 pc. | 50 pcs | 40 boxes |
| 811012 | 5.1 cm x 7.6 cm | 1 pc. | 100 pcs | 20 boxes |
| 811022 | 5.1 cm x 7.6 cm | 1 pc. | 50 pcs | 40 boxes |

# entrance mat

## non-sterile

**features:**

- material used for the production of the mat foil layers: low-density polyethylene resins
- resin (foil component) is made with the use of modern high-pressure technology, which allows excluding catalysts in the form of heavy metals from the production process. Thus the foil sheets do not contain detectable quantities of cadmium, chloride, sodium or lead. Acryl-based elastic adhesive substance is free of ingredients coming into reaction with metals. The top and bottom sheets are also made of polyolefin, they are not adhesive
- characterized by adhesive properties
- each layer has bacteriostatic coating
- 30 thin adhesive sheets
- low mat profile: app. 2 mm thick
- adhesive bottom layer prevents unwanted mat movement
- no need to clean the mat - as soon as the surface of the mat is contaminated, it should be torn off to uncover a new, clean layer
- small numbered labels in the mat corner facilitate removal of subsequent layers

**indication:**

- preventing spreading of contamination brought on shoe soles and wheelchairs to operating rooms

| ref. | dimensions | intermediate packaging | bulk packaging |
|---|---|---|---|
| M001 | 45 x 115 cm | 10 pcs | 5 x 10 pcs |

# microscope slides

## non-sterile

**features:**

- made of high-quality transparent glass
- dimensions meet international standards
- flat, smooth and solid surface
- allow to obtain good quality smears
- box wrapped in foil for additional protection against humidity
- dimensions: 76 mm x 26 mm x 1 mm

**indication:**

- to hold specimens for microscopic study

| ref. | type | packaging unit / box | bulk packaging |
|---|---|---|---|
| SP-01 | plain, unground edges | 50 pcs | 50 x 50 pcs |
| SP-11 | twin frosted at one end, ground edges | 50 pcs | 50 x 50 pcs |

# wooden tongue depressor


**features:**
- made of birch wood
- rounded edges preventing injuries
- long outreach thanks to appropriate length
- available in sterile (EO sterilization) and non-sterile version
- sterile depressor packed individually in paper pouch
- individual packaging of the sterile depressor: paper

**indication:**
- diagnostic examination of the oral cavity

| ref. | size | type | sales unit | bulk packaging |
|---|---|---|---|---|
| SLN-001 | 15 cm x 1.7 cm | non-sterile | 100 pcs | 50 x 100 pcs |
| SLS-001 | 15 cm x 1.7 cm | sterile | 100 pcs | 20 x 100 pcs |

# PE gloves

## non-sterile

**features:**
- made of polyethylene
- coarse surface and tear-resistant weld
- ambidextrous
- elongation min. 130%
- tensile strength min.10 MPa
- available in two sizes: M - female, L - male
- approved for contact with food
- packaging in a bag enabling individual removal of gloves
- single-use

**indication:**
- intended for use as a contribution to other gloves (double-gloving) and for minimally invasive procedures such as drug preparation, feeding the patient

| ref. | size | packaging unit | bulk packaging |
|---|---|---|---|
| RF-M | M | 100 pcs | 100 x 100 pcs |
| RF-L | L | 100 pcs | 100 x 100 pcs |

# PE apron

## non-sterile

**features:**
- made of polyethylene
- transparent
- thickness: 0.02 mm (20 µm)
- single-use
- individual packaging: foil

**indication:**
- it is intended for medical staff as an additional protection in wet procedures, such as preparing medicines, washing the patient, feeding the patient

| ref. | size | intermediate packaging | bulk packaging |
|---|---|---|---|
| FF–71X116 | 71 x 116 cm | 100 pcs | 10 x 100 pcs |
| FF-71X180 | 71 x 180 cm | 100 pcs | 10 x 100 pcs |

LNE
Le progrès, notre passion à partager

Certification
Médical-Santé

Notified Body N° 0459

**ATTESTATION** / *CERTIFICATE* / CERTIFICADO **N° 9554 rev. 8**

**Délivrée à Paris le 04 mai 2018**

*Issued in Paris on May 4th, 2018*

Establecido en Paris, el 04 mayo 2018

# ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

**Approbation du Système d'assurance Qualité de la Production (limitée à l'obtention et au maintien de l'état stérile)**

*Approval of Production Quality Assurance System (related to securing and maintening sterile conditions)*

Aprobación del sistema de garantía de calidad de la producción (limitado a la obtención y al mantenimiento del estado estéril)

**ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux**

*ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices*

ANEXO V punto 3 Directiva 93/42/CEE relativa a los productos sanitarios

**Fabricant** / *Manufacturer* / Fabricante

## VYGON
## 5 rue Adeline
## 95440 ECOUEN FRANCE

**Catégorie du(des) dispositif(s)** / *Device(s) category* / Categoría del producto

**Cathéters, sondes, tubes, accessoires et dispositifs pour perfusion, anesthésie, réanimation, nutrition, gastro-entérologie, urologie, chirurgie, drainage, voies respiratoires et hémodialyse.**

*Catheters, probes, tubes, accessories and devices for infusion, anesthesia, reanimation, enteral feeding, gastro-enterology, urology, surgery, drainage, respiratory tract and haemodialysis.*

Catéteres, sondas, tubos, accesorios y dispositivos para perfusión, anestesia, reanimación, alimentación, gastro-enterología, urología, cirugía, drenaje, vías respiratorias y hemodiálisis.

Voir détails sur addendum / See attachment for additional information

**Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177278, le système d'assurance qualité - pour l'obtention et le maintien de l'état stérile - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.**

*LNE/G-MED certifies that, on the basis of the results contained in the file referenced P177278, the quality system - for the quality system for securing and maintaining sterile conditions - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex V section 3.*

El LNE/G-MED certifica que después del examen de los resultados indicados en el expediente P177278, el sistema de calidad para el diseño, para la obtención y el mantenimiento del estado estéril - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo V punto 3 de la Directiva 93/42/CEE

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

**Début de validité** / *Effective date* / Fecha efectiva : **May 4th, 2018 (included)**

**Valable jusqu'au** / *Expiry date* / Fecha de expiración : **May 9th, 2021 (included)**

**On behalf of the G-MED Certification Director**
**Béatrice LYS**
**G-MED Certification Technical Director**
**Por delegación para el Director de Certificación G-MED**

LNE - 9554 rev. 8
Renouvelle le certificat 9554-7

Digitally signed by Grabazei Alexandru
Date: 2019.04.03 11:33:37 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Grabazei Alexandru
Date: 2019.03.11 18:06:49 EET
Reason: MoldSign Signature
Location: Moldova

GMED_b5e_ESP-V3-01-2013

LNE
Le progrès, une passion à partager

Certification
Medical Device

**Addendum au certificat n° 9554 rev. 8** **page 1/1**
*Addendum of the certificate n° 9554 rev. 8*
Dossier / *File* N° P177278

## Identification des dispositifs / *Identification of devices*

**Les produits couverts par ce certificat sont référencés sur la liste des produits (9 pages) authentifiée par le LNE/G-MED en date du 22 novembre 2017.**
*Medical devices covered by this certificate are referenced on the manufacturer's list of products (9 pages) authenticated by LNE/G-MED dated November 22, 2017.*

**********

## Identification des sites et activités / *Identification of locations and activities*

- **VYGON - 5 rue Adeline - 95440 ECOUEN – France.**
  - **Siège social, Commercialisation, management de la stérilisation.**
  - *Headquarters, Marketing, Sterilization management.*
- **VYGON - Parc Alata – 5 avenue des bouleaux – 60550 VERNEUIL EN HALATTE – France**
  - **Stérilisation et Distribution**
  - *Sterilization and Distribution.*
- **DIMEQUIP - Route de BAVAY - FRAMERIES 7080 – Belgique**
  - **Fabrication.**
  - *Manufacturing.*
- **SAP – 14 rue des Fontaines - 59880 SAINT SAULVE – France**
  - **Fabrication.**
  - *Manufacturing.*
- **SIPA - 22 avenue Stroh - 59440 AVESNES SUR HELPE – France**
  - **Fabrication.**
  - *Manufacturing.*
- **SIPV – 5 rue Adeline - 95440 ECOUEN – France.**
  - **Fabrication.**
  - *Manufacturing.*
- **VYGON Portugal : Parque Empresarial de Baltar/Parada – Rua F 7585-013 Baltar – Paredes – Portugal.**
  - **Fabrication et commercialisation.**
  - *Manufacturing and marketing.*

| LNE/G-MED | 0459 |
|---|---|

Laboratoire national de métrologie et d'essais LNE

**On behalf of the G-MED Certification Director**
**Béatrice LYS**
**G-MED Certification Technical Director**


**Laboratoire national de métrologie et d'essais** • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

TÜVRheinland®

# Certificate

**The Certification Body of**
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**ZARYS International Group**
**Spolka z ograniczona**
**odpowiedzialnoscia**
**spolka komandytowa**
**ul. Pod Borem 18**
**41-808 Zabrze**
**Poland**

has established and applies a quality management system for medical devices for the following scope:

**Production and distribution of disposable and reusable medical devices and distribution of in-vitro medical devices (see attachments for sites included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

| | |
|---|---|
| Effective Date: | 2017-11-07 |
| Certificate Registration No.: | SX 60120471 0001 |
| An audit was performed. Report No.: | 26300232 006 |
| This Certificate is valid until: | 2020-06-08 |

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-11-07

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

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

**Attachment to Certificate**
**Registration No.:** SX 60120471 0001
**Report No.:** 26300232 006

**Organization:**
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

**Scope:**

Sites included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity:
Production, storage and distribution of medical devices

**Certification Body**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**Date: 2017-11-07**

**Maciej Sciera**

TÜVRheinland®

# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

**Registration No.:** DD 60100191 0001

**Report No.:** 26300232 002

**Manufacturer:**
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

**Products:** (see attachment for products included)

Replaces Certificate, Registration No.: DD 60098972 0001

**Expiry Date:** 2019-06-08

**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:** 2015-03-02

**Date:** 2015-03-02

**Notified Body**

**D. Swiatko**

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**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

**Attachment to Certificate**
**Registration No.:** DD 60100191 0001
**Report No.:** 26300232 002

**Manufacturer:**
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

- Sterile and non-sterile cutting gauze
- Sterile and non-sterile gauze swabs
  (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
  (with or without X-ray thread)
- Sterile and non-sterile lap sponges
  (with or without X-ray thread)
- Non-sterile folded gauze
- Sterile paraffin gauze dressings
- Sterile oxygen masks
- Sterile non-rebreathe masks
- Sterile nebulizer masks
- Sterile Multi-Vent masks
- Sterile oxygen tubing
- Sterile nebulizer sets
- Sterile suction catheters
- Sterile three-way stopcocks
- Sterile infusion sets for single use
- Sterile extension tubes

**Notified Body**

TÜV Rheinland LGA Products GmbH – TÜVRheinland – Zertifizierungsstelle

**Date: 2015-03-02**

**D. Swiatko**

TÜVRheinland®

Doc. 2/4, Rev. 0

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

**Attachment to Certificate**
**Registration No.:** DD 60100191 0001
**Report No.:** 26300232 002

**Manufacturer:**
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

- Sterile hypodermic needles
- Sterile endotracheal tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Sterile tracheostomy tubes
- Sterile laryngeal masks
- Sterile nasal oxygen cannulas
- Sterile urology catheters
- Sterile feeding tubes
- Sterile syringes for single use
- Sterile transfusion sets for single use
- Sterile and non-sterile gauze balls (with or without X-ray thread)
- Sterile and non-sterile gauze rolls (with or without X-ray thread)
- Sterile surgical suction sets
- Sterile surgical suction cannulas

**Notified Body**

TÜV Rheinland LGA Products GmbH – TÜVRheinland – Zertifizierungsstelle

**Date: 2015-03-02**

**D. Swiatko**

TÜVRheinland®

Doc. 3/4, Rev. 0

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

**Attachment to Certificate**
**Registration No.:** DD 60100191 0001
**Report No.:** 26300232 002

**Manufacturer:**
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Surgical gowns
- Incise films
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Surgical drapes
- Eye pads
- Transparent film dressings
- Foam dressings
- Vaginal speculums
- Urine bags
- Absorbent wound dressings
- Fluid collection pouches

**Notified Body**

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

**D. Swiatko**

**Date: 2015-03-02**

TÜVRheinland®

Doc. 4/4, Rev. 1

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

**Attachment to Certificate**
**Registration No.:** DD 60100191 0001
**Report No.:** 26300232 003

**Manufacturer:**
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Nelaton catheters
- Cervical brushes
- Tongue depressors
- Intubation stylets
- Tracheal tube holders
- Guedel airways
- Suction tubes
- Alginate dressings
- Withdrawal cannulas

**Notified Body**

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

**Date: 2016-02-02**

M.Aihara

**M.Sc. M. Aihara**

# CERTIFICAT

*CERTIFICATE OF REGISTRATION*

CERTIFICADO

**N° 9567 rev. 11**

**Le LNE certifie que le système de management de la qualité développé par**

*LNE certifies that the quality management system developed by*

LNE certifica que el sistema de gestión de la calidad desarollado por

**VYGON**

**5 rue Adeline**

**95440 ECOUEN FRANCE**

**pour les activités** / *for the activities* / para las actividades

**Conception, fabrication, commercialisation de dispositifs médicaux et accessoires, stériles ou non, à usage unique.Formation des utilisateurs.Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène de dispositifs médicaux selon l'EN ISO 11135-1:2007.Voir Addendum**

*Design, manufacturing and sales of sterile or no sterile single use medical devices and accessories and Training of users. Validation and routine control for ethylene oxide sterilization of medical devices according to EN ISO 11135-1:2007.See Addendum*

Diseño, fabricación y comercialización de dispositivos médicos y accesorios, estériles y no estériles, descartables y Formación dellos usuarios. Validación y control de rutina de la esterilización al óxido de etileno de dispositivos médicos según él EN ISO 11135-1:2007. Ver Anexo

**réalisées sur le(s) site(s)** *performed on the location(s)* / que se realizan en

**Voir addendum** / *See addendum* / Ver anexo

**est conforme aux exigences des normes internationales**

*complies with the requirements of the international standards*

es conforme a las exigencias de las normas internacionales

## NF EN ISO 13485 : 2016 - ISO 13485 : 2016

**Début de validité** / *Effective date* / Fecha efectiva : **May 4th, 2018 (included)**

**Valable jusqu'au** / *Expiry date* / Fecha de expiración **May 9th, 2021 (included)**

**Etabli le** / *Issued on* / Fecha de preparación **May 4th, 2018**

Digitally signed by Andrei Alexandru
Date: 2019.04.03 11:32:57 EEST
Reason: MoldSign Signature
Location: Moldova

**On behalf of the G-MED Certification Director**

**Beatrice LYS**

**G-MED Certification Technical Director**

**Por delegación para el Director de Certificación G-MED**

LNE N° 9567–11

Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification

Renouvelle le certificat 9567-10

Accréditation n°4-0038
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ_ESP_plus3sites-V4-05-2013

**Ce certificat couvre les activités et les sites suivants :**
*This certificate covers the following activities and sites :*
Este certificado es aplicable a las actividades e instalaciones siguientes:

**Activités** / *activities/* actividades :

**Version française :**

- **Conception, fabrication et commercialisation de dispositifs médicaux et accessoires, stériles et non stériles, à usage unique destinés :**
  - **aux abords vasculaires, à l'hémodialyse, à l'anesthésie loco-régionale,**
  - **aux abords des voies digestives, rectales, urinaires et respiratoires,**
  - **au drainage chirurgical et thoracique,**

  **et Formation des utilisateurs dans le domaine de l'accès vasculaire.**
- **Conception, fabrication et commercialisation de champs et renforts absorbants en non tissé, de films adhésifs, de trousses composites, de vêtements, accessoires et instruments pour le bloc opératoire.**
- **Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène de dispositifs médicaux selon l'EN ISO 11135-1 : 2007.**

*Version anglaise :*

- *Design, manufacturing and sales of sterile or no sterile single use medical devices and accessories, for :*
  - *vascular access, haemodialysis, local anaesthesia,*
  - *digestive, rectal, urinary and respiratory access,*
  - *thoracic and surgical drainage,*

  *and Training of users in the field of vascular access.*
- Design, manufacturing and sales of non woven absorbent drapes and strengthening drapes, adhesif films, composite kits, dressing, accessories and instruments for operating room
- *Validation and routine control for ethylene oxide sterilization of medical devices according to EN ISO 11135-1: 2007.*

Version espagnole :

- Diseño, fabricación y comercialización de dispositivos médicos y accesorios , estériles y no estériles, descartables para :
  - acceso vascular, hemodiálisis, anestesia locoregional,
  - acceso de las vías digestivas, rectales, urinarias y respiratorias,
  - drenaje quirúrgico y torácico,

  y Formación dellos usuarios en acceso vascular.
- Diseño, fabricación y comercialización de campos y refuerzos absorbentes sin tejer, filmes apósitos, estuches compuestos, ropa, accesorios y instrumentos para el quirófano.
- Validación y control de rutina de la esterilización al óxido de etileno de dispositivos médicos *según él EN ISO 11135-1 : 2007.*

**On behalf of the G-MED Certification Director**
**Béatrice LYS**
**G-MED Certification Technical Director**


**Laboratoire national de métrologie et d'essais** • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié par l'autorité compétente française en matière de dispositifs médicaux n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

**Sites & Activités/** *locations & Activities* / Instalaciones e actividades

- **VYGON - 5 rue Adeline - 95440 ECOUEN – France**
  **Siège social, Responsable de la mise sur le marché, Conception, Commercialisation, management de la stérilisation**
  *Headquarters, Legal manufacturer, Design, Marketing, Sterilization management*
  Responsible de la puesta en el Mercado, Diseño, Marketing, Gestión de la esterilización

- **VYGON - Parc Alata – 5 avenue des bouleaux – 60550 VERNEUIL EN HALATTE – France**
  **Stérilisation et Distribution**
  *Sterilization and Distribution*
  Esterilización, Distribución

- **DIMEQUIP - Route de BAVAY - FRAMERIES 7080 – Belgique**
  **Fabrication**
  *Manufacturing*
  Fabricación

- **SAP – 14 rue des Fontaines - 59880 SAINT SAULVE – France**
  **Fabrication**
  *Manufacturing*
  Fabricación

- **SIPA - 22 avenue Stroh - 59440 AVESNES SUR HELPE – France**
  **Fabrication**
  *Manufacturing*
  Fabricación

- **SIPV – 5 rue Adeline - 95440 ECOUEN – France**
  **Fabrication**
  *Manufacturing*
  Fabricación

- **VYGON Portugal : Parque Empresarial de Baltar/Parada – Rua F 7585-013 Baltar – Paredes – Portugal**
  **Fabrication et commercialisation**
  *Manufacturing and marketing*
  Fabricación, Marketing

**********

**7 sites** / 7 *locations* / 7 Instalaciones

**On behalf of the G-MED Certification Director**
**Béatrice LYS**
**G-MED Certification Technical Director**


**Laboratoire national de métrologie et d'essais** • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié par l'autorité compétente française en matière de dispositifs médicaux n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



# Certificate

## Certificato CE del Sistema di Garanzia della Qualità/ *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

# GIMA S.p.A.

**sede operativa** / Operational Headquarter:
Via Marconi, 1
20060 Gessate, MI - Italia

**sede legale**
Via Tommaso Grossi, 2
Milano - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*
Bilancia ad uso medicale / *Scales for medical use*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per misurazione / *Measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Elettrocardiografi / *Electrocardiographs*
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi

CE

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

**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
www.kiwacermet.it

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1106

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Aspiratori e accessori / *aspirators and accessories*

**Tipologia /** *Medical Devices:*
Bilancia ad uso medicale / *Scales for medical use*

**Classe di rischio /** *Risk class:*
I m

**Codice NANDO /** *NANDO codes:*
MD 0104

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

ASTRA - FAMILY - PEGASO

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Classe di rischio /** *Risk class:*
I s

**Codice NANDO /** *NANDO codes:*
MD 7006

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Gimabrush

Chief Operating Officer
Giampiero Belcredi

**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
www.kiwacermet.it

CERMET

CE

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Cervical Spoon

**Modello /** *Model:*
Cervix Brush Plush

**Modello /** *Model:*
Gima Collector

**Modello /** *Model:*
Gimabrush Ball

**Modello /** *Model:*
Kit ORL sterile / *Sterile ENT kit*

**Modello /** *Model:*
Kit pap test / *Pap smear kit*

**Modello /** *Model:*
Spatula legno sterile / *Sterile wooden spatula*

**Modello /** *Model:*
Spatula plastica sterile / *Sterile plastic spatula*

**Modello /** *Model:*
Speculum perno - mix / *Vaginal Speculum central pin - mix*

**Modello /** *Model:*
Speculum perno centrale - grande / *Vaginal Speculum central pin- large*

**Modello /** *Model:*
Speculum perno centrale - medio / *Vaginal Speculum central pin - medium*

**Modello /** *Model:*
Speculum perno centrale - piccolo / *Vaginal Speculum central pin - small*

Chief Operating Officer
Giampiero Belcredi

CE

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

**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
www.kiwacermet.it

CERMET

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Speculum tache - mix / *Vaginal Speculum tache - mix*

**Modello /** *Model:*
Speculum vite centrale - mix / *Vaginal Speculum middle screw - mix*

**Modello /** *Model:*
Speculum vite laterale - grande / *Vaginal Speculum side screw - large*

**Modello /** *Model:*
Speculum vite laterale - medio / *Vaginal Speculum side screw - medium*

**Modello /** *Model:*
Speculum vite laterale - mix / *Vaginal Speculum side screw - mix*

**Modello /** *Model:*
Speculum vite laterale - piccolo / *Vaginal Speculum side screw - small*

**Modello /** *Model:*
Swab plastica sterile / *Sterile plastic swab*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 7006

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Proctoscopio adulti / *Adult proctoscope*

**Modello /** *Model:*
Proctoscopio pediatrico / *Pediatric proctoscope*

Chief Operating Officer
Giampiero Belcredi

CE

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

**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
www.kiwacermet.it

CERMET

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1102

**Marca /** *Brandname:*
AKOD PHARMA

**Modello /** *Model:*
AEROSOL A PISTONE

**Modello /** *Model:*
AEROSOL AD ULTRASUONI

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
AEROSOL MISTRAL

**Modello /** *Model:*
AEROSOL A PISTONE

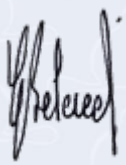
**Modello /** *Model:*
AEROSOL A PISTONE CORSIA

**Modello /** *Model:*
AEROSOL A PISTONE EOLO

**Modello /** *Model:*
AEROSOL AD ULTRASUONI


**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
www.kiwacermet.it


Chief Operating Officer
Giampiero Belcredi



**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1302

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

PULSOSSIMETRO / *PULSE OXIMETER*

**Tipologia /** *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1302

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale classico Farmamed / *Classic digital Farmamed thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Farmamed / *Digital Farmamed thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Linea F flessibile / *Digital linea F thermometer flexible*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed / *NUB Farmamed Digital thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed Baby / *NUB Farmamed Baby Digital thermometer*

Chief Operating Officer
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CE

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

**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
www.kiwacermet.it

CERMET

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmamed / *Farmamed ecologic thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico linea F / *Linea F ecologic thermometer*

**Marca /** *Brandname:*
CARREFOUR GS

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Carrefour / *Digital Carrefour thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale GS / *Digital GS thermometer*

**Marca /** *Brandname:*
CRAF

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale classico Linea F / *Classic digital linea F thermometer*

**Marca /** *Brandname:*
FederFARMA.co

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Profar / *Profar ecologic thermometer*

**Marca /** *Brandname:*
GABBIANO

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Farmasan / *Farmasan Digital thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmasan / *Farmasan ecologic thermometer*

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*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale / *Digital thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB / *NUB Digital thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico / *Ecologic thermometer*

**Marca /** *Brandname:*
PB PHARMA

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale / *Digital GS thermometer*

**Marca /** *Brandname:*
QUIDNOVI PHARMA

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico TECNICO Eco / *TECNICO Eco ecologic thermometer*

**Marca /** *Brandname:*
SSL HEALTHCARE

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro clinico Realcheck mercury free / *Clinical thermometer Realcheck mercury free*

**Marca /** *Brandname:*
T&B

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale 36.2 T&B / *Digital 36.2 T&B thermometer*

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**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per misurazione / *Measuring devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1302

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Altimetro - Plicometro - Metro per neonati / *Height meter - Skinfold caliper - Baby measuring meter*

**Tipologia /** *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1102

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Cannule di Guedel sterili / *Sterile Guedel airways*

**Modello /** *Model:*

Kit pallone silicone adulti / *Silicone resuscitator kit - adult*

**Modello /** *Model:*

Maschere laringee riutilizzabili / *Reusable laryngeal mask airways*

**Modello /** *Model:*

Mascherina per rianimazione CPR / *CPR resuscitator mask*

**Modello /** *Model:*

Palloni rianimatori / *Resuscitators*

**Modello /** *Model:*

Accessori -Maschere in silicone autoclavabili / *Silicone autoclavable face masks*

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## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Accessori -Maschere in silicone con cuscinetto e cuffia autoclavabili / *Silicone autoclavable cushion face masks*

**Modello /** *Model:*

Accessori -Maschere ossigeno / *Oxygen masks*

**Modello /** *Model:*

Accessori -Mascherine monouso PVC a cuscino d'aria iniettabile / *Disposable PVC injectable air cushion face masks*

**Modello /** *Model:*

Accessori -Occhiali ossigeno / *Nasal cannula*

**Modello /** *Model:*

Accessori -Tubo ossigeno / *Oxygen tubing*

**Modello /** *Model:*

Accessori -Valvola PEEP / *Peep valve*

**Tipologia /** *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1403

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Ghiaccio istantaneo monouso Farmamed Gelo Pack / *Farmamed disposable instant ice cold pack*

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*Notified Body nr. 0476*

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Ghiaccio istantaneo monouso / *disposable instant ice cold pack*

**Modello /** *Model:*

Ghiaccio istantaneo PE / *PE instant ice cold pack*

**Modello /** *Model:*

Ghiaccio istantaneo TNT / *TNT instant ice cold pack*

**Marca /** *Brandname:*
MENARINI

**Modello /** *Model:*

Ghiaccio istantaneo monouso Menarini / *Menarini disposable instant ice cold pack*

**Tipologia /** *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1302

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

ECG PALMARE

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**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

**Classe di rischio /** *Risk class:*
II a

**Codice NANDO /** *NANDO codes:*
MD 1302

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*
SFIGMO DIGITALE DA POLSO ROSS ANGELINI

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS ANGELINI

**Marca /** *Brandname:*
AKOD PHARMA

**Modello /** *Model:*
SFIGMO DIGITALE DA BRACCIO HL AKOD

**Modello /** *Model:*
SFIGMO DIGITALE DA POLSO HL AKOD

**Modello /** *Model:*
SFIGMO DIGITALE DA TAVOLO HL AKOD

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
a mercurio -STAR

**Modello /** *Model:*
a mercurio -YTON

**Modello /** *Model:*
a mercurio -YTON PLAUNAZIDE

**Modello /** *Model:*
Aneroidi -BOSTON

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*Notified Body nr. 0476*

Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Aneroidi -BOSTON COMBISARTAN

**Modello /** *Model:*
Aneroidi -BOSTON LATEX-FREE

**Modello /** *Model:*
Aneroidi -BOSTON LOBIVON

**Modello /** *Model:*
Aneroidi -BOSTON VALPRESSION

**Modello /** *Model:*
Aneroidi -BOSTON OLPRESS

**Modello /** *Model:*
Aneroidi -DALLAS

**Modello /** *Model:*
Aneroidi -GIMATONO

**Modello /** *Model:*
Aneroidi -LONDON

**Modello /** *Model:*
Aneroidi -ROMA

**Modello /** *Model:*
Aneroidi -SIRIO

**Modello /** *Model:*
Aneroidi -TOKIO

**Modello /** *Model:*
Aneroidi -TOKIO ZANTIPRESS

**Modello /** *Model:*
Aneroidi -YTON

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| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



Certificate

## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
digitali -AUTOMATICO DA POLSO

**Modello /** *Model:*
digitali -24h

**Modello /** *Model:*
digitali -AMBULATORIALE

**Modello /** *Model:*
digitali -AUTOMATICO DA BRACCIO

**Modello /** *Model:*
digitali -DOMINO

**Modello /** *Model:*
digitali -SENZA MERCURIO

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO HL GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA POLSO HL GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA POLSO ROSS GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA TAVOLO HL GIMA

**Modello /** *Model:*
digitali -YTON DIGITALE

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**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

**Kiwa Cermet Italia S.p.A.**
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CERMET

Certificate

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|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

**Kiwa Cermet Italia S.p.A.**
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Chief Operating Officer
Giampiero Belcredi

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Number | 10164 - M | Valid From | 2018-10-01 |
| First issue date | 2012-10-15 | Last change date | 2018-10-01 |
| Valid until | 2021-10-14 | | |

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:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

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

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

**Kiwa Cermet Italia S.p.A.**
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www.kiwacermet.it

**GIMA S.p.A.**
**Registered Headquarters**
- Via Grossi, 2 20121 Milano Italia

**Certified Sites**
- Via Marconi, 1 20060 Gessate ( MI ) Italia

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

# BOTTLE 4 l WITH COVER - autoclavable 121°

| | |
|---|---|
| **Code:** | **28228** |
| **Category:** | **Jars** |
| **Unit of sale:** | **1 pc.** |
| **Minimum order:** | **1** |
| **Type:** | **Medical device** |
| **Class:** | **II A** |
| **NSIS:** | **590904** |
| **CND:** | **Z120105** |
| **EAN13:** | **8023279282283** |

**Description:** **121°C autoclavable jar 4l with overflow system**
**To be used with 4 l aspirators.**

# MEDICAZIONE PLUS TROLLEY

| | |
|---|---|
| **Code:** | **45800** |
| **Category:** | **Stainless steel trolleys** |
| **Unit of sale:** | **1 pc.** |
| **Minimum order:** | **1** |
| **Type:** | **No medical device** |

**EAN13:** **8023279458008**

**Description:**

**Medicazione Plus trolley with removable trays.**

**Stainless steel frame, mounted on castors Ø 80 mm.**
**Size: 61 x 43 xh 78 cm.**
**Weight: 10 kg.**
**Maximum load (x shelf): 10 kg.**
**Delivered in kit form.**
**Made in Italy.**