GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.05 09:44:47 EET
Reason: MoldSign Signature
Location: Moldova

DECLARAȚIE DE CONFORMITATE

Societatea GIMA S.P.A., cu sediul administrativ în Gessate (MI), Via Marconi 1 și sediul social în Milano, Via Tommaso Grossi 2, în calitate de producător al dispozitivului medical:

Număr unic de înregistrare GIMA (SRN):

Dispozitiv medical (nume și denumire)	Cod	Cod UDI-DI de bază
BAZINET ÎN FORMĂ DE BOABĂ DE FASOLE 254x141x33 mm	26611	80232790000V04020400000 RQ

Clasă de risc I (nesteril), conform reglementării 1 Anexa VIII la Regulamentul (UE) 745/2017 (MDR), declară, pe propria răspundere exclusivă, că acest dispozitiv:

- a fost realizat în conformitate cu cerințele esențiale și cu prevederile Regulamentului (UE) 745/2017 (MDR), așa cum reiese din dosarul tehnic arhivat la sediul firmei;
- nu s-au utilizat specificații comune pentru conformitatea dispozitivului medical sus-menționat;

Gessate, 5/28/2021

GIMA S.p.A.
Reprezentant legal(Nicola Manzoni)

S/S KIDNEY DISH - 254x141x33 mm

Code:	**26611**
Category:	**Stainless steel holloware**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1925317**
CND:	**V0402**
EAN13:	**8023279266115**

Description:

Stainless Steel AISI 304 holloware with thickness 0.6 mm.

Kidney dish 18/8 - shallow - tray 10"

- **Size: 254 x 141 x 33 mm**
- **Capacity: 750 ml**

Technical Specifications:

- **Autoclavable 121°C**
- **AISI 304**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 690080**

Issued To: **GVS Filter Technology UK Limited**
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

In respect of:

Manufacture of sterile heat and moisture exchanger (HME) filters and attachments, heat and moisture exchanger and bacterial/viral (HMEF) filters and attachments, electrostatic filters and attachments, pleated mechanical filters and attachments for anaesthesia, ventilation, respiratory and critical care; sterile activated carbon and surgical smoke evacuation filters; for vent, suction, insufflation and irrigation applications.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-11-21** Date: **2021-05-13** Expiry Date: **2023-11-20**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 690080

Issued To:

GVS Filter Technology UK Limited
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

Number		**Device Subcategory**	**Intended purpose per IFU**
Class IIa			
NBOG code	MD 0101	HME devices for anaesthesia, respiratory and critical care/HMEF filters and attachments for anaesthesia, respiratory and critical care	NA
NBOG code	MD 0101	Electrostatic filters and attachments for anaesthesia, respiratory and critical care/pleated mechanical filters and attachments for anaesthesia, respiratory and critical care	NA
NBOG code	MD 0101	Activated carbon and smoke evacuation filters	NA
NBOG code	MD 0101	Vent suction insufflation and irrigation	NA

First Issued: **2018-11-21** Date: **2021-05-13** Expiry Date: **2023-11-20**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 690080**
Date:	**2021-05-13**
Issued To:	**GVS Filter Technology UK Limited** **NFC House** **Vickers Industrial Estate** **Mellishaw Lane** **Morecambe** **Lancashire** **LA3 3EN** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park, Bellshill ML4 3NJ United Kingdom	**ETO Sterilization**
GVS S.P.A. Via Roma 50 Zola Predosa (BO) 40069 Italy	**EU Representative**
GVS Technology (Suzhou) Co., Ltd. No. 602 Changjiang Road Fengqiao Civil-Run Scitech Park Suzhou New District Suzhou Jiangsu 215129 China	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 690080**

Date: **2021-05-13**

Issued To: **GVS Filter Technology UK Limited**
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

Date	Reference Number	Action
21 November 2018	8902128	First Issue.
27 February 2019	8943588	Traceable to NB 0086.
Current	3371294	Addition of EU Representative to List of Significant Subcontractors.

GVS Filter Technology UK – Legal Manufacturer
Medical Air Filtration Division
NFC House
Vickers Industrial Estate
Mellishaw Lane
LA3 3EN

Tel: +44 (0) 1524 847600
www.gvs.com

E C Declaration of Conformity

We declare that the undernoted Class IIa Medical Devices are in conformity with the essential requirements and provisions of EC Directive 93/42/EEC and following changes (2007/47/EEC), Annex V Harmonised Standards.

Device Description
Products as per attached product schedule.

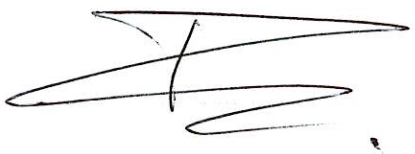
Directives:
Medical Devices Directive 93/42/EEC via the route of Annex V, products are Class IIa, UK Statutory Instrument SI 618 2002 and other applicable standards and regulatory requirements listed in Section 7 of the GVS Filter Technology – Medical Air Filtration Division technical data file.

Certificate number 690080 issued by BSI Group, The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands with Notified Body Number 2797.

EU Authorised Representative: GVS S.p.A, Via Roma 50, 40069 Zola Predosa, Bologna, Italy.

This Declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Signed by



Paulo Raquel
GVS UK Managing Director

Date: 25/05/21

Product Schedule

Category 1 – HME Devices for anaesthesia, respiratory and critical care/HMEF filters for anaesthesia Respiratory and critical care

4244/03	ECO MAXI Pleat
4244/711	MAXI HME Pleat
4244/712	MAXI HME Pleat Without Port
4244/761	Eco-therm HEPA filter with coil paper HME
4331/01	ECO HMEF
4331/01DFK	Eco HMEF With Connectors
4331/01DGK	Eco HMEF With Connectors
4331/50	ECO Maxi HME
4333/01	Eco HMEF
4333/01BNK	Eco HMEF and elbow
4333/01DBK	Eco HMEF + tube + connectors
4333/01DEK	Eco HMEF + tube + connectors
4333/01DDK	Eco HMEF + tube + connectors
4333/01DFK	HMEF, Luer Lid with Expandable Tube
4333/01DGK	Eco HMEF with connectors
4333/50	ECO Maxi Straight HME
4333/710	MAXI Angled HMEF
4333/711	MAXI Straight HMEF
4333/712	MAXI Straight HMEF
4333/712BNK	MAXI Straight HMEF + elbow
4333/714	ECO Maxi Angled HMEF
4333/721	Eco Range HMEF (white foam)
4333/750	MAXI Angled HME
4333/751	MAXI HME
4333/752	ECO Maxi HME
4333/754	ECO Maxi Angled HME
4333/760	Eco MAXI angled coil paper HMEF
4333/761	Eco MAXI straight coil paper HMEF
4333/770	Eco MAXI angled coil paper HME
4333/771	Eco MAXI straight coil paper HME
4333/772	Eco MAXI straight coil paper HME
8866/50	Comfort fit HME
8866/100	Comfort fit HMEF
8866/100DEK	Comfort fit HMEF + tube + connectors
9064/711	MIDI HMEF
9064/711BNK	MIDI HMEF + elbow
9064/751	MIDI HME
9064/761	Eco MIDI straight coil paper HMEF

9065/710	MIDI Angled HMEF
9065/750	MIDI Angled HME
9065/760	Eco MIDI angled coil paper HMEF
9065/770	Eco MIDI angled coil paper HME
9066/711	MINI HMEF
9066/751	MINI HME
9066/761	Eco MINI straight coil paper HMEF
9067/710	MINI Angled HMEF
9067/750	MINI Angled HME
9067/760	Eco MINI angled coil paper HMEF
9080/100	Neo-natal HMEF
9080/100BNK	Neo Natal HMEF with elbow
9080/710	MICRO MINI angled HMEF
9080/750	MICRO angled HME
9085/751	MICRO Lo-Volume HME
9085/771	ECO Micro Lo-Volume coil paper HME
9500/01	Tracheal HME
9500/03	Tracheal Blue HME
9500/04	Tracheal HME
9500/710	Micro tracheal
9500/750	Micro Tracheal
A540	Elbow with sampling port
A541	Elbow without sampling port
A542	Double Swivel Elbow
A543	Double Swivel Elbow
A620/40/61	Expandable Tubing with Gas Sampling Elbow
A620/41/61	Expandable Tubing with Elbow
A620/42/61	Expandable Tubing with Double Swivel Elbow and Port
A620/43/61	Expandable Tubing with Double Swivel Elbow
A620/60/61	Attachment

Category 2 – Electrostatic filters and attachments for anaesthesia, respiratory and critical care/Pleated mechanical filters and attachments for anaesthesia, respiratory and critical care.

1200/08	Medipleat Autoclavable Filter
1200/20	Medipleat Autoclavable Filter
1210/09	Autoclavable Filter
1420/01	Medguard
1420/03	Medguard
1420/03BOK	Medguard + Connector
2800/01	Spiroguard
2800/01BFK	Spiroguard with Nose Clip
2800/01BMK	Spiroguard with Bite Grip
2800/01DAK	Spiroguard with Nose Clip and Bite Grip
2800/01DHK	Spiroguard with Bite Grip, Mouthpiece, Nose Clip
2800/01DJK	Spiroguard with Mouthpiece and Nose Clip
2800/02	Spiroguard
2800/02BFK	Spiroguard with Nose Clip
2800/02BWK	Spiroguard with Mouthpiece
2800/02DAK	Spiroguard with Nose Clip and Bite Grip
2800/03	

2800/03BFK	Spiroguard with Nose Clip
2800/03DAK	Spiroguard with Nose Clip and Bite Grip
2800/03DJK	Spiroguard with Mouthpiece and Nose Clip
2800/10	Spiroguard
2800/10DAK	Spiroguard with Nose Clip and Bite Grip
2800/21	Spiroguard Integral Mouthpiece
2800/21BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/22	Spiroguard
2800/22BFK	Spiroguard with Nose Clip
2800/22DAK	Spiroguard with Nose Clip and Bite Grip
2800/23	Spiroguard with Integral mouthpiece side
2800/24	Spiroguard
2800/25	Spiroguard with Integral mouthpiece
2800/26	Spiroguard
2800/27	Spiroguard with Integral Mouthpiece
2800/30	Spiroguard Integral Mouthpiece
2800/31	Spiroguard Integral Mouthpiece
2800/31BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/32	Spiroguard
2800/728	Compact Electrostatic Spirometry Filter
2800/729	Compact Electrostatic Spirometry Filter
2800/R1	Spiroguard Re-usable
2800/R2	Spiroguard Re-usable
2800/R3	Spiroguard Re-usable
2802/01	Spiroguard Adaptor
2802/02	Spiroguard Adaptor
2802/03	Spiroguard Adaptor
2802/04	Spiroguard Adaptor
2802/05	Spiroguard Adaptor
2802/06	Spiroguard Adaptor
2802/07	Spiroguard Adaptor
2802/08	Spiroguard Adaptor
2802/09	Spiroguard Adaptor
2802/10	Spiroguard Adaptor
2802/11	Spiroguard Adaptor
2802/12	Spiroguard Adaptor
2802/13	Spiroguard Adaptor
2802/14	Spiroguard Adaptor
2802/15	Spiroguard Adaptor
2802/16	Spiroguard Adaptor
2802/17	Spiroguard Adaptor
2802/18	Spiroguard Adaptor
2802/19	Spiroguard Adaptor
2802/20	Spiroguard Adaptor
2802/21	Spiroguard Adaptor
2802/22	Spiroguard Adaptor
2802/23	Spiroguard Adaptor
2802/24	Spiroguard Adaptor
2802/25	Spiroguard Adaptor
2802/26	Spiroguard Adaptor

2802/27	Spiroguard Adaptor
2802/28	Spiroguard Adaptor
2802/29	Spiroguard Adaptor
2802/30	Spiroguard Adaptor
2802/31	Spiroguard Adaptor
2802/32	Spiroguard Adaptor
3000/03	Multi-vent
3000/04	Multi-vent tapered
3000/07	Multi-vent
3000/11	Multi-vent flat top
3000/12	Multi-vent flat top
3000/740	Expiratory Filter
4020/01	ECO Machine Filter
4020/03	Single Walled Machine Filter
4020/06	ECO Machine Filter
4020/10	Machine Filter
4220/01	Eco maxipleat
4220/04	ECO Filter
4222/01	ECO slimline
4222/01BWK	Eco slimline and mouthpiece
4222/01DFK	Eco slimline, Luer Lid + Expandable Tube
4222/01DDK	Eco slimline+tube+connectors
4222/02	ECO slimline
4222/02BWK	Eco slimline and mouthpiece
4222/03	ECO slimline
4222/700	MAXI Maxi Angled Filter
4222/701	Eco Maxi Filter
4222/702	MAXI Maxi Filter
4222/703	MAXI Maxi Filter
4244/01	Eco maxi-pleat
4244/01DBK	Pleated filter and collapsible tube
4244/01DEK	Maxi Pleat with connectors
4244/02	ECO Maxi Pleat
4244/04	ECO maxi-pleat
4244/06	ECO maxi-pleat
4244/700	MAXI Maxi Angled Pleat
4244/701	Eco Maxi Pleat
4244/702	MAXI Maxi Pleat
4444/01	Slimline Bacterial/Viral
4444/01BWK	Slimline Electrostatic with mouthpiece
4444/06	Slimline Electrostatic with Integral Mouthpiece
4444/66	Ultra-High Efficiency Slimline
6888/01	Maxi pleat/2
6888/20	Maxi pleat
6888/21	Maxi Pleat ULPA Filter
8444/01	Maxi pleat/1
8444/27	Maxi pleat
8866/01	Comfort fit bacterial/viral
9066/701	MINI Filter
9066/701BNK	MINI Filter + elbow

9067/700	MINI Angled Filter
9080/01	Neo-natal/Bacterial/Viral
9080/700	MICRO Angled Filter
A539	Bitegrip Mouthpiece
A571	Mouthpiece

Category 3 – Activated Carbon and Smoke Evacuation Filters.

2200/47	Smoke Filter
2200/47BBK	Smoke Set
2200/47BDK	Smoke Set
2200/947	90mm Smoke Evacuation Filter

Category 4 – Vent, Suction, Insufflation and Irrigation

2000/01	Vent filter
2000/02	Vent Filter - Autoclavable
2000/05	Vent Filter
2000/05BAK	Vent Filter Set
2000/05DLK	Vent Filter Set
2000/05DTK	Vent Set
2000/05DUK	Vent Set
2000/05DWK	Vent Set
2000/05DXK	Vent Set
2000/06	Vent Filter
2000/07	Vent Filter - Autoclavable
2000/08	Vent Filter
2000/09	Vent Filter
2000/12	Vent Filter
2000/16	Vent Filter
2000/17	Vent Filter
2000/18	Vent filter
2000/18BEK	Vent Set
2000/20	Vent Filter
2000/22	Transducer filter
2000/31	Vent Filter
2000/35	Vent filter
2000/37	Vent filter
2000/38	Vent filter
2000/39	Vent Filter
2000/42	Vent Filter
2000/53	Suction Filter
2200/01	Insufflation Filter
2200/01BCK	Insufflation Set
2200/01DKK	Insufflation Set
2200/02	Suction Filter
2200/02DIK	Suction Set
2200/05	Insufflation Filter
2200/05BRK	Insufflation Set

2200/06	Suction Filter
2200/15	Insufflation Filter
2200/16	Suction Filter
2200/21	Suction Filter
2200/25BUK	Insufflation Set
2200/25DSK	Insufflation Set
2200/26	Suction Filter
2200/33	Insufflation Filter
2200/35	Suction Filter
2200/36	Suction Filter
2200/48	Insufflation filter
2200/48BIK	Insufflation Set
2200/55	Suction Filter
2200/56	Insufflation Filter
2200/62BHK	Insufflation Set
2200/65	Insufflation filter
2200/70	Suction Filter
2200/902	90MM Suction Filter
2200/911	90MM Suction Filter
6421/04	Insufflation Filter
6421/04BGK	Hi Flow Insufflation Kit
6421/04DVK	Insufflation Set

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:	**1281843**
CND:	**A0680**
EAN13:	**8023279282399**

Description:

Hydrophobic, antibacterial filter
Compatible with: SuperVega on trolley, Clinic, Clinic Plus

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.

Base and small balls made of non-toxic polypropylene. Central part made of copolymer non-toxic. Tube and mouthpiece made of polyethylene.

Multilingual box and instructions: GB, FR, IT, ES, PT, DE, GR, Arabic.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARAȚIE DE CONFORMITATE

Societatea GIMA S.P.A., cu sediul administrativ în Gessate (MI), Via Marconi 1 și sediul social în Milano, Via Tommaso Grossi 2, în calitate de producător al dispozitivului medical:

Număr unic de înregistrare GIMA (SRN):

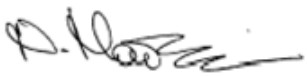
Dispozitiv medical (nume și denumire)	Cod	Cod UDI-DI de bază
RESPIPROGRAM - gimnastică respiratorie	33442	802327900Y030327C400000MB

Clasă de risc I (nesteril), conform reglementării 1 Anexa VIII la Regulamentul (UE) 745/2017 (MDR), declară, pe propria răspundere exclusivă, că acest dispozitiv:

- a fost realizat în conformitate cu cerințele esențiale și cu prevederile Regulamentului (UE) 745/2017 (MDR), așa cum reiese din dosarul tehnic arhivat la sediul firmei;
- nu s-au utilizat specificații comune pentru conformitatea dispozitivului medical sus-menționat;

Gessate, 5/28/2021

GIMA S.p.A.
Reprezentant legal(Nicola Manzoni)



Ministero della Salute

Dipartimento della innovazione
Direzione Generale dei farmaci e dei dispositivi medici
Ufficio III - Dispositivi medici – V.le G. Ribotta, 5 – 00144 Roma
Tel. 06.5994.1 PEC: dgfdm@postacert.sanita.it

Roma, 27 Gennaio 2011

DGFDM.III/P/2875/I.1.b.f.1/2011/110

Assessorati alla Sanità delle
Regioni e Province Autonome
di Trento e Bolzano
LORO SEDI

ASSOBIOMEDICA
Viale Pasteur, 10
00144 ROMA

FOFI
Via Palestro, 75
00185 ROMA

ASSOPRESIDI
Piazzale Ardigò, 30
00142 ROMA

CONSOBIOMED
Piazza G. Marconi, 23
41037 MIRANDOLA (MO)

AISPEC
Via G. Da Procida, 11
20149 MILANO

S.I.F.O.
Via Carlo Farini, 81
20159 Milano

F.I.F.O.
Via Properzio, 5
00161 Roma

e p.c.

Ufficio di Gabinetto
SEDE

OGGETTO: Prodotti utilizzati per la detersione e l'igiene dei pazienti.

I prodotti in oggetto, in genere presentati sotto forma di *manopole o spugne, anche pre-saponate*, vengono utilizzati anche in ambito ospedaliero per l'igiene e pulizia dei pazienti.

Risulta che varie aziende fabbricanti hanno marcato CE tali prodotti come dispositivi medici, ai sensi del D.lgs. 46/97 (attuazione della direttiva 93/42/CE), ed hanno inserito gli stessi nella Banca Dati dei dispositivi medici di questo Ministero.

A tal proposito si fa presente che i prodotti di cui trattasi, alla luce della loro destinazione d'uso e della definizione di dispositivo medico di cui all'art.1, c.2 lettera a), del predetto decreto, non rientrano nell'ambito di applicazione del decreto stesso e, pertanto, non devono recare la marcatura CE di dispositivo medico. Peraltro il medesimo concetto, per quanto riguarda i prodotti cosmetici e per l'igiene della persona, è espresso nella Linea Guida europea MEDDEV 2.1/1 (Aprile 1994), in particolare al punto 1.1 lettera d).

Al fine di garantire una omogenea applicazione della direttiva sopracitata, questa Direzione sta richiedendo alle aziende fabbricanti che hanno marcato CE tali prodotti di eliminare il predetto marchio CE dagli stampati e di non definire i prodotti stessi come dispositivi medici.

Le SS.LL. sono invitate a dare ampia diffusione della presente nota presso tutti i soggetti interessati (fabbricanti, produttori terzisti, distributori ed utilizzatori dei prodotti in questione).

IL CAPO DIPARTIMENTO
F.to Dott. Romano Marabelli

SOAPED WASH GLOVE

Code: 36663

Category: Personal hygienic and disinfectant products

Unit of sale: box of 50 pcs.

Minimum order: 1

Type: No medical device

EAN13: 8023279366631

Description:

Disposable mitten to wash patient.
Made in non woven and sponge, soaked with liquid soap with neutral PH and anallergenic.
Ideal for patient cleaning and hygiene.

Size: 15x25 cm.

CERTIFICATO

Reg. Numero	10164 - A	Valido da	2021-10-14
Primo rilascio	2012-10-15	Ultima modifica	2021-10-14
Scadenza	2024-10-14	Settore IAF	29 a

Certificato del Sistema di Gestione per la Qualità

ISO 9001:2015

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:

GIMA S.p.A.

è conforme alla norma UNI EN ISO 9001:2015 per i seguenti prodotti/servizi:

Commercializzazione, confezionamento ed assistenza di: dispositivi medici (DM), diagnostici in vitro (IVD), dispositivi di protezione individuale (DPI), biocidi (PMC), dispositivi per veterinaria, accessori, arredi e supporti ad uso medico

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Il presente certificato è costituito da 1 pagina.

GIMA S.p.A.
Sede Legale
- Via Grossi, 2 20121 Milano - Italia

Sedi Oggetto di Certificazione
- Via Marconi, 1 20060 Gessate (MI) - Italia

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.kiwa.it

SGQ N° 007A

CERTIFICATE

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
www.kiwa.it

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

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

CERTIFICATO

Reg. Numero	10164 - M	Valido da:	2021-10-14
Primo rilascio	2012-10-15	Ultima modifica	2021-10-14
Scadenza	2024-10-14		

Certificato del Sistema di Gestione per la Qualità

ISO 13485:2016

Si dichiara che il Sistema di Gestione per la Qualità dell'Organizzazione:

GIMA S.p.A.

è conforme alla norma UNI CEI EN ISO 13485:2016 per i seguenti prodotti/servizi:

Gestione della progettazione e della produzione, confezionamento e assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: iniezione, infusione, trasfusione, dialisi; disinfezione, pulizia, risciacquo; IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi e accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: circolazione extracorporea, infusione, emaferesi; stimolazione o inibizione; riabilitazione e protesi attive; IVF e ART; software; sistemi di gas medicali e relative parti); Dispositivi di monitoraggio; Dispositivi per immagini e termoterapia (eccetto: radiazioni ionizzanti, litotripsia); Diagnostici in vitro (IVD).
Commercializzazione e assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi e accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: IVF e ART), Dispositivi per acquisizione immagini (eccetto radiazioni ionizzanti), Dispositivi di monitoraggio, Dispositivi per radioterapia e termoterapia (eccetto: radiazioni ionizzanti, litotripsia); Diagnostici in vitro (IVD).

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Riferirsi al manuale qualità per i dettagli delle esclusioni ai requisiti della norma UNI CEI EN ISO 13485:2016.

Il presente certificato è costituito da 1 pagina.

GIMA S.p.A.
Sede Legale
- Via Grossi, 2 20121 Milano Italia

Sedi Oggetto di Certificazione
- Via Marconi, 1 20060 Gessate (MI) Italia

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

CERTIFICATE

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)

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.

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