Certificate

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Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1023642-1
Certificate Holder:	ChM sp. z o.o. Lewickie 3b 16-061 Juchnowiec Kościelny Poland
Scope:	Design and development, manufacture, distribution and service of orthopaedic implants, non-active surgical instruments, medical drives and attachments, tourniquet control units. Sterilization of medical devices by hydrogen peroxide. Manufacture of orthopaedic implants using Selective Laser Melting (SLM) technology. Manufacture of class III custom-made implantable devices.

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.:	84971449-30
Effective date:	2024-04-13
Expiry date:	2027-04-12
Issue date:	2024-04-09

Replaces certificate SX 1023642-1 issued 2022-02-04

This certificate can be validated on https://www.certipedia.com

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland® Precisely Right.

ST/504A

ChM®

TOURNIQUET
Cat. No. 30.0008÷30.0019

www.chm.eu

All comments should be addressed to

ChM sp. z o.o. Lewickie 3b,16-061 Juchnowiec K., Poland
tel. +48 85 86 86 100, fax: +48 85 86 86 101
www.chm.eu e-mail: chm@chm.eu

Document No ST/504A
Date of issue 02.06.2007
Review date P-001-19.11.2018

Product name	**The range of use** (*limb circumference in cm*)	**Dimensions**	**Cat. No**
Single arm tourniquet	25÷40	64x13	30.0009
Single tourniquet for children	14÷20	50x6	30.0010
Dual tourniquet for children	14÷20	50x11	30.0011
Single femoral tourniquet	38÷58	85x14	30.0012
Single femoral tourniquet	38÷58	120x13.5	30.0013
Single femoral tourniquet	38÷58	140x13.5	30.0008
Conical single femoral tourniquet	40÷60	110x11	30.0014
Single arm tourniquet long	38÷58	82x8	30.0015
Single arm tourniquet	25÷40	62x7	30.0016
Single tourniquet for babies	10÷17	30x3	30.0017
Dual torniquet	38÷58	84x16	30.0018
Dual torniquet	25÷40	64x13	30.0019

Tab. 1. Description of available tourniquets

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec K., POLAND
tel. +48 85 86 86 100 fax +48 85 86 86 101 e-mail: chm@chm.eu

1. INDICATIONS FOR USE

Tourniquet, in combination with an external source of compressed air or nitrogen, is used to control blood flow in the limb and produce a bloodless surgical field. Tourniquet control unit or hand pump (*compressed air*) produced by **ChM** may be examples of external source of compressed air or nitrogen.

2. CONTRAINDICATIONS

- Open fracture of the lower limb.
- Post-traumatic hand reconstruction.
- Severe crush injuries.
- Elbow surgery (*with excessive swelling*).
- Severe hypertension.
- Skin grafts in which all bleeding points must be distinguished.
- Compromised circulation e.g. peripheral arterial disease.
- Diabetes.
- Sickle cell disease is a relative contraindication against use of a tourniquet (*See PRECAUTIONS*).
- Avoid using a tourniquet in patients undergoing secondary or delayed treatment after fixation.

NOTE:
The abovementioned list of contraindications is not exhaustive.

3. USE

Depending on the area of application and the type of surgical procedure, tourniquets of different structure may be used so that they are more effective. **ChM** offers several types of tourniquets differing in shape, length and width, allowing the surgeon to choose a tourniquet appropriate to the location and type of procedure to be performed.

3.1. PLACE OF USE

The tourniquet shall be applied on a limb at the place of a large muscle mass which helps to protect vessels and nerves from damage.

The typical location of the tourniquet:

- arms and thighs - where the limb has the the largest circumference closest to the operation field
- forearm - the central part of the forearm
- shank - the proximal edge of the tourniquet should be placed on the largest circumference of the calf
- foot - 1/3 of the lower part of the shank with the distal edge of the tourniquet passing above the ankle

3.2. SINGLE AND DUAL TOURNIQUETS

Depending on the surgical procedure, single or dual tourniquets may be used. Single tourniquets are mostly used with general anesthesia, brachial plexus blocks and central blocks.

Dual tourniquets are mostly used with local intravenous anesthesia (*also called Bier's block*). Thanks to the independent inflation of the proximal and distal section of the tourniquet, the surgical procedure is more patient-friendly, especially during longer operations.

3.3. LENGTH

The length of a tourniquet is chosen on the basis of the length of the limb circumference measured at the point where the tourniquet is to be applied. Knowing the circumference of the limb and the place of application, select the tourniquet from the table (*Tab. 1*).

NOTE:
Use of excessively short or long tourniquets can lead to its unstable positioning on a limb, problems with full occlusion of blood vessels and damage to the skin.

3.4. WIDTH

As wide as possible tourniquets should be applied. A wider tourniquet requires lower occlusion pressure than a narrow one what reduces the risk of complications associated with its use.

3.5. TOURNIQUET PRESSURE

Tourniquet pressure used during surgery depends on many variables which include: the patient's age, skin condition, a place the tourniquet is applied, the shape and size of the tourniquet. According to the publicly available literature data, occlusion pressure:

- for the upper limb should be about 75÷100mmHg above systolic blood pressure,
- for the lower limb should double the value of systolic blood pressure.

3.6. PREPARING A PATIENT FOR SURGERY

Each patient that is scheduled for surgery with the use of a tourniquet, should undergo a preoperative evaluation including, inter alia: determination of the physical condition of the patient, a medical history and medication review. On the basis of the preoperative evaluation, possible complications that may occur during the surgery are determined and whether the patient is allowed to be treated with the use of the tourniquet. The measurement of the blood pressure and the length of the limb at the point where the tourniquet will be applied should also be performed preoperatively.

3.7. TOURNIQUET USE

Carefully check the condition and tightness of the tourniquet prior to each use. Should a defect or doubts as to the condition of the tourniquet appear, it is unacceptable to continue the use of the tourniquet. Service and warranty repairs may be performed only by the manufacturer - **ChM**.

Apply disposable protective cuff on the selected preoperatively tourniquet that would protect the tourniquet from blood, body fluids or other infectious agents contamination. The skin under the tourniquet should be protected from direct exposure to that tourniquet by applying padding underneath, keeping in mind though that excessively thick padding may increase occlusion pressure. Moreover, do not allow any fluids to get under the tourniquet because they can cause skin injuries. When applying the tourniquet, make sure that the surfaces that come into direct contact with the padding (*skin*) were not wrinkled because it can lead to skin damage after inflating the tourniquet. Applied tourniquet should adhere to the limb with its entire perimeter. The tourniquet feeder should be placed outside of the limb and operating field. Avoid accidental pressure of the feeder on nerves or its bend. Connect the tourniquet to a tourniquet control unit and start inflating until the established occlusion pressure is reached. Inflating the tourniquet should proceed quickly and smoothly so that arteries and veins

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are closed at the same time.

As a general accepted rule, the maximum time of the tourniquet being inflated (*without its deflating*), in the case of a healthy adult patient, should not exceed 120 minutes. During the surgery, to reduce the risk of complications, intraoperative control of blood pressure, the pressure in the tourniquet and the time the tourniquet is applied should be conducted.

Before deflating the tourniquet, it is recommended to close the wound. Deflating the tourniquet before wound closure increases blood loss. Deflating the tourniquet should proceed quickly and smoothly. After deflating, immediately remove the tourniquet and the padding from the limb so that they will not block the return of venous blood and resultant blood accumulation in the operating field.

4. SIDE EFFECTS

After tourniquet use, dull ache in the limb may appear.
Prolonged ischemia caused by use of the tourniquet can lead to temporary or permanent damage to tissues, blood vessels and nerves and can cause changes in blood clotting.

Excessively high pressure in the tourniquet can cause paralysis of limbs.
Excessively low pressure in the tourniquet can cause passive congestion of limbs with possible irreversible loss of function.

Intraoperative bleeding may be caused by:

- blood remaining in the limb due to insufficient emptying the limb of blood
- the use of improper occlusion pressure
- blood penetrating from the nourishing vessels of the long bones.

5. CONSTRUCTION

The tourniquet is made of polyamide fabric.

The latex bladder connected with feeder is placed in the tourniquet pocket.

The quick-fit port connecting the tourniquet to the tourniquet control unit is placed at the end of the feeder. The tourniquet is reinforced by silicone insert to obtain greater stiffness.

There are special Velcro and protective tapes on the inner side of the cuff to protect the tourniquet against loosening when applied on the limb and inflated.

6. DISINFECTION AND CLEANING

The tourniquet should be cleaned by hand with a soft brush damped in warm water and a small amount of soap causing no foaming, unless the tourniquet got contaminated with infectious agents, e.g. blood. Only exterior surfaces of the rubber feeder and cuff should be cleaned, avoiding the excessive soaking of the tourniquet material. It is not allowed to: immerse the tourniquet in the water or aqueous solutions of washing and disinfecting agents, machine-wash the tourniquet or to pull out the inner latex bladder from the cuff. Wipe the washed tourniquet with a damp lint-free cloth and air-dry (*do not roll*). When dried, the tourniquet may be wiped with cloths soaked in isopropyl alcohol.

Should the tourniquet have contact with infectious agents, e.g. blood, for cleaning and disinfection use mild washing and disinfecting agents approved for use with medical devices. Follow the instructions provided by the manufacturer of these agents. It is recommended to use aqueous solutions of washing or washing-disinfecting agents with a pH value between 7 and 10.8.

1. Remove blood and/or dirt from the product using disposable cloths or paper towels.
2. Prepare a fresh detergent solution using e.g., Neodisher MediClean Forte from Dr.Weigert at a temperature of 40°C ± 2, using 15ml of the agent per 1l of water. Thoroughly clean the surface of the cuff with a soft, lint-free cloth.
3. Dry the device thoroughly using disposable, soft, lint-free cloth.
4. Prepare an aqueous solution of disinfectant, e.g. Neodisher Septo Active from Dr.Weigert of 2% concentration (*20g of agent per 1 liter of water*) and temperature 20°C ± 2. Thoroughly clean the surface of the cuff with a soft, lint-free cloth.
5. After disinfecting, clean the tourniquet with a damp cloth to remove residual solution that may have an allergic and irritating effect and shorten the life of the product. Dry the tourniquet in the open air - do not roll.
6. Clean the tourniquet with cloths soaked in isopropyl alcohol.

NOTE:
The tourniquet, when used in surgery, should always be placed in a protective cuff which protects it from contamination by infectious agents.

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7. STORAGE

The tourniquet shall be stored unwound or slightly twisted in a roll, in a dry, not in direct sunlight place. The tourniquet storage should be preceded by its washing and thorough drying.

8. WARRANTY AND SERVICE

The manufacturer provides annual warranty for the usage of the tourniquet provided that the above principles are observed.

Unauthorised changes introduced by the user might render the warranty void.

ChM sp. z o.o. does not specify the maximum number of cycles for use of tourniquets. The tourniquet life is dependent on many factors, including the duration of each use, the pressures used, re-processing.

Each time before re-use, inspect the functionality of the product. In case of damage, the tourniquet must not be used for surgery.

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CE

eurofins | Product Testing

CERTIFICATO DEL SISTEMA DI GESTIONE
MANAGEMENT SYSTEM CERTIFICATE

Certificato No *Certificate No.*	**EPT 25 ISO 13485 0069**
Si attesta che *We declare that:*	**VIVOSTAT A/S**
Sede legale *Registered office:*	Borupvang n. 2, 3450 Allerød, Denmark
Unità operative *Operative unit:*	Borupvang n. 2, 3450 Allerød, Denmark
Il sistema di qualità: *The quality system*:	È conforme ai requisiti della norma dei sistemi di gestione *Has been found to conform to the management system standard* EN ISO 13485:2016 + A11/2021
Questa certificazione è valida per il seguente campo applicativo *This certificate is valid for the following produce or service range*:	Progettazione, produzione e assistenza di dispositivi medici per sistemi di trattamento e somministrazione del sangue e relativi accessori. Distribuzione di dispositivi medici sterili e non sterili per chirurgia e area spinale. *Design, manufacturer and servicing of medical devices for blood processing and delivery systems and associated accessories.* *Distribution of medical device sterile and not sterile in the surgical instruments, spinal area.*
Aree tecniche *Technical Areas*	1.1.A, 1.1.E, 1.2.A, 1.5.A, 1.5.C, 1.5.D, 1.6.A, 1.6.B, 1.7.E

Storia del certificato
Certificate history

Il presente certificato sostituisce i precedenti / *This certificate replaces the previous ones.*

Certificato / *Certificate*	Descrizione / *Description*
EPT 25 ISO 13485 0069 01/06/2025 – 31/05/2028	Prima emissione / First issue Rinnovo del certificato EPT 24 ISO 13485 0043 – 08/08/2024-31/05/2025 Azienda con sistema di gestione qualità certificata dal 17-05-2001 con l'OdC Bureau Veritas con ultimo triennio 01-06-2022 / 31-05-2025 *Renewal of the Certificate EPT 24 ISO 13485 0043 – 08/08/2024-31/05/2025* *Company with quality management system certified since 17-05-2001 with Bureau Veritas Certification Body with last cycle 01-06-2022 / 31-05-2025.*

Data di prima emissione / *First issue date (dd-mm-year):*	**08-08-2024**
Luogo e data emissione corrente / *Place and date corrent issue (dd-mm-year):*	**Torino, 01-06-2025**
Il Certificato è valido dal / *The Certificate is valid from (dd-mm-year):*	**01-06-2025**
Il Certificato è valido fino al / *The Certificate is valid until (dd-mm-year)*:	**31-05-2028**

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

MANAGEMENT SYSTEM CERTIFICATION ACCREDIA

00054

Paolo Dentis
Responsabile di schema
Scheme Responsible

Paolo Trisoglio
Amministratore Delegato
Managing Director

Vivostat®

DECLARATION OF CONFORMITY

Issue date: 2024-09-19 | Previous issue date: 2023-06-29

Vivostat operates a full quality assurance system in accordance with Annex II of the Medical Devices Directive 93/42/EEC, + Amendment directive 2007/47/EEC.

We, the manufacturer, hereby declare, under our sole responsibility, that the products as listed below are in conformity with the provisions of the Directive 93/42/EEC, amended by Directive 2007/47/EEC.

This is to confirm that the Vivostat® System complies with the Essential Requirements as laid down in Annex I of the Medical Devices Directive.

The devices are manufactured by or for: Vivostat A/S, Borupvang 2, 3450 Alleroed, Denmark

Notified body:
- Identification no.: 0477
- Name: Eurofins Product Testing Italy Srl

This Declaration of Conformity includes the following devices:

Device purpose	Device trade name	Ref. no.	Class	Rule (Annex IX)	Date CE Marking was first applied
Preparation	Vivostat Fibrin Preparation kit	VS 306	III	Rule 13/17	2003-06-19
	Vivostat PRF Preparation kit	VS 406	III	Rule 13/17	2003-06-19
	ArthroZheal® Preparation Kit	AZ 506	III	Rule 13/17	2022-02-28
	Vivostat processor PRO 800	PRO 800	IIa	Rule 2/3	2010-09-29
	Vivostat processor PRO 800 Compact	PRO 800-5	IIa	Rule 2/3	2024-09-18
Application	Vivostat Spraypen kit	VS 305	IIa	Rule 2	2001-05-17
	Vivostat Spraypen kit Concorde	VS 315	IIa	Rule 2	2003-08-13
	Vivostat Endoscopic kit	VS 325	IIa	Rule 6	2002-05-08
	Vivostat Endoscopic kit – straight	VS 345	IIa	Rule 6	2002-05-08
	Vivostat Split kit	VS 510	IIa	Rule 2	2014-04-24
	Vivostat applicator APL 400	APL 400	IIa	Rule 11	2010-09-29
Co-Delivery	Vivostat Spraypen kit Co-delivery	VS 335	IIa	Rule 2	2003-06-19
	Vivostat Endoscopic kit – Co-delivery	VS 355	IIa	Rule 6	2002-05-08
	Vivostat applicator APL 404	APL 404	IIa	Rule 11	2010-09-29
Procedure Sets	Vivostat Fibrin Set	VS 302	III	Combination	2003-06-19
	Vivostat Fibrin Set – Concorde	VS 312	III	Combination	2003-06-19
	Vivostat Fibrin Set – Co-delivery	VS 322	III	Combination	2003-06-19
	Vivostat Fibrin Set – Endoscopic	VS 323	III	Combination	2003-06-19
	Vivostat PRF Set	VS 400	III	Combination	2003-06-19
	Vivostat PRF Set – Concorde	VS 410	III	Combination	2003-06-19
	Vivostat PRF Set – Endoscopic	VS 420	III	Combination	2003-06-19
	Vivostat PRF Set – Co-delivery	VS 422	III	Combination	2003-06-19
	Vivostat Obsidian ASG	GM 700	III	Combination	2003-06-19
	Vivostat Obsidian ASG – Endo	GM 720	III	Combination	2018-02-20
	Vivostat Obsidian RFT	GM 740	III	Combination	2018-02-20
	ArthroZheal® Set	AZ 500	III	Combination	2022-02-28
	ArthroZheal® Set – Endoscopic	AZ 520	III	Combination	2022-02-28

The Preparation Kits, the Application Kits and the Procedure Sets contain the following components under mutual compatibility declaration under article XII of Medical Devices Directive 93/42/EEC, + Amendment directive 2007/47/EEC;

- Vasuflo Scalp Vein Set, Ref no. 40018, CE0123
- B.Braun Needle, 21G, Ref no. 4657527, CE0123
- B.Braun Medical Replacement Cap, Ref no. 474900, CE0123
- RoweSpike II, Ref no. A-6425, CE0482
- Ovesco Fistula Brush, Ref no. 200.65, CE0124
- BD Microlance 3, Ref no. 300637. CE0050

On behalf of Vivostat A/S:

Marko M. Rackovic, CEO

Il certificato è stato rilasciato in precedenza da un altro CAB.
The certificate has been issued previously by another CAB.

CISQ is a member of

IQNET
The International Certification Network
www.iqnet-certification.com

CERTIFICATO N. **ICIM-13485-050862-02**
CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GIMA S.P.A.

SEDE CENTRALE / *HEADQUARTER*

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Gestione della Progettazione, della Fabbricazione ed Immissione sul Mercato di: Dispositivi per la Misurazione dei Parametri Fisiologici, Dispositivi per Ginecologia ed Odontoiatria, Dispositivi per Aerosolterapia, Dispositivi per Rianimazione ed Assistenza Respiratoria, Dispositivi per Terapia Termica, Strumentario Chirurgico, Monitor Multiparametrici, Diagnostici in Vitro. Commercializzazione di: Dispositivi Medici (DM) e Diagnostici in Vitro (IVD).

Management of the Design, Manufacturing and Placing on the market of: Devices for the Measurement of Physiological Parameters, Devices for Gynecology and Dentistry, Devices for Aerosol Therapy, Devices for Resuscitation and Respiratory Assistance, Devices for Thermal Therapy, Surgical Instruments, Multiparametric Monitors, In Vitro Diagnostics. Marketing of: Medical Devices (DM) and In Vitro Diagnostics (IVD).

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
15/10/2012	15/10/2024	14/10/2027

Vincenzo Delacqua
Rappresentante Direzione / *Management Representative*
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0004

CISQ
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.

0860CM_06_IT

Allegato al CERTIFICATO N. **ICIM-13485-050862-02**
Attachment to CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GIMA S.P.A.

Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:
In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:

VIA MARCONI, 1 20060 GESSATE MI IT - Italia	Gestione della Progettazione, della Fabbricazione ed Immissione sul Mercato di: Dispositivi per la Misurazione dei Parametri Fisiologici, Dispositivi per Ginecologia ed Odontoiatria, Dispositivi per Aerosolterapia, Dispositivi per Rianimazione ed Assistenza Respiratoria, Dispositivi per Terapia Termica, Strumentario Chirurgico, Monitor Multiparametrici, Diagnostici in Vitro. Commercializzazione di: Dispositivi Medici (DM) e Diagnostici in Vitro (IVD), Dispositivi di Protezione Individuale (DPI), Biocidi (PMC), Dispositivi per Veterinaria, Accessori, Arredi e Supporti ad Uso Medico.
VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia	Sede Legale.

Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Management of the Design, Manufacturing and Placing on the market of: Devices for the Measurement of Physiological Parameters, Devices for Gynecology and Dentistry, Devices for Aerosol Therapy, Devices for Resuscitation and Respiratory Assistance, Devices for Thermal Therapy, Surgical Instruments, Multiparametric Monitors, In Vitro Diagnostics. Marketing of: Medical Devices (DM) and In Vitro Diagnostics (IVD).

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2024-10-15**
First issued on: **2012-10-15**
Expires on: **2027-10-14**

Registration Number:
IT-149833 ICIM-13485-050862-02

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:
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 **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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Annex 1 to IQNET Certificate Number:

IT-149833 ICIM-13485-050862-02

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

List of additional locations:

VIA MARCONI, 1 20060 GESSATE MI IT - Italia
VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia

This annex is only valid in connection with the original certificate number mentioned above.

CISQ is a member of

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CERTIFICATO N. **ICIM-9001-050863-01**
CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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SEDE CENTRALE / *HEADQUARTER*

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PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

IAF: 29

Commercializzazione 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.

Marketing of: Medical Devices (MD), In Vitro Diagnostics (IVD), Personal Protective Equipment (PPE), Biocides (PMC), Veterinary Devices, Accessories, Furnishings and Supports for Medical Use.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
15/10/2012	15/10/2024	14/10/2027

Vincenzo Delacqua
Rappresentante Direzione / *Management Representative*

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0004

CISQ
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.

Allegato al CERTIFICATO N. **ICIM-9001-050863-01**
Attachment to CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GIMA S.P.A.

Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:
In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:

VIA MARCONI, 1 20060 GESSATE MI IT - Italia	Gestione della Progettazione, della Fabbricazione ed Immissione sul Mercato di: Dispositivi per la Misurazione dei Parametri Fisiologici, Dispositivi per Ginecologia ed Odontoiatria, Dispositivi per Aerosolterapia, Dispositivi per Rianimazione ed Assistenza Respiratoria, Dispositivi per Terapia Termica, Strumentario Chirurgico, Monitor Multiparametrici, Diagnostici in Vitro. Commercializzazione di: Dispositivi Medici (DM) e Diagnostici in Vitro (IVD), Dispositivi di Protezione Individuale (DPI), Biocidi (PMC), Dispositivi per Veterinaria, Accessori, Arredi e Supporti ad Uso Medico.
VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia	Sede Legale.

Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Marketing of: Medical Devices (MD), In Vitro Diagnostics (IVD), Personal Protective Equipment (PPE), Biocides (PMC), Veterinary Devices, Accessories, Furnishings and Supports for Medical Use.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2024-10-15**
First issued on:	**2012-10-15**
Expires on:	**2027-10-14**

Registration Number:

IT-149834 ICIM-9001-050863-01

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:
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 **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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Annex 1 to IQNET Certificate Number:

IT-149834 ICIM-9001-050863-01

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

List of additional locations:

VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia

This annex is only valid in connection with the original certificate number mentioned above.

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

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

EU DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A. (single registration number (SRN): IT-MF-000011004), with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milan, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Product and trade name	Product code	Basic UDI-DI
S/S COMMODE BUCKET WITH COVER - 5 l	26574	80232790000V04021600010T6
S/S BUCKET WITH COVER - 12 l	26576	80232790000V04020000010Q7
S/S BUCKET WITH COVER - 15 l	26577	80232790000V04021700010TK
S/S KIDNEY DISH - deep - 162x77x31 mm	26580	80232790000V04020400010RT
S/S KIDNEY DISH - deep - 207x98x39 mm	26581	
S/S KIDNEY DISH - deep - 247x122x43 mm	26582	
S/S KIDNEY DISH - deep - 309x149x59 mm	26583	
S/S KIDNEY DISH WITH LID - 200x95x35 mm	26584	
S/S KIDNEY DISH WITH LID - 247x122x43 mm	26585	
S/S WASH BASIN diam. 310 x h 72 mm	26586	
S/S WASH BASIN diam. 318 x h 84 mm	26587	80232790000V04021600010T6
S/S WASH BASIN diam. 405 x h 95 mm	26588	
S/S KIDNEY DISH WITH LID - 309x149x59 mm	26589	80232790000V04020400000RQ
S/S GALLIPOT diam.107 mm	26595	80232790000V04021400010SC
S/S GALLIPOT diam.158 mm	26596	
S/S INSTRUMENT TRAY - 380X304X50 mm	26597	80232790000V04026400010UZ
S/S INSTRUMENT TRAY - 440X320X64 mm	26598	
S/S INSTRUMENT TRAY - 223X126X45 mm	26599	
S/S DENTAL TRAY - 208X109X15 mm	26600	
S/S INSTRUMENT TRAY - 210X160X25 mm	26601	
S/S INSTRUMENT TRAY - 264X172X47 mm	26602	
S/S INSTRUMENT TRAY - 306X196X50 mm	26603	
S/S INSTRUMENT TRAY - 355X254X50 mm	26604	
S/S INSTRUM. TRAY WITH LID - 223x126x45 mm	26605	
S/S INSTRUM. TRAY WITH LID - 264x172x47 mm	26606	
S/S INSTRUM. TRAY WITH LID - 306x196x50 mm	26607	
S/S INSTRUM. TRAY WITH LID - 355x254X50 mm	26608	
S/S INSTRUM. TRAY WITH LID - 440x320X64 mm	26609	

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S/S KIDNEY DISH - 207x128x33 mm	26610	80232790000V04020400000RQ
S/S KIDNEY DISH - 254x141x33 mm	26611	
S/S KIDNEY DISH - 280x141x33 mm	26612	
S/S MAYO TRAY - 254x165x18 mm	26613	80232790000V08996400010BC
S/S MAYO TRAY - 350x252x16 mm	26614	
S/S MAYO TRAY - 432x295x19 mm	26615	
S/S GALLIPOT WITH LIP diam. 56 mm	26616	80232790000V04021400010SC
S/S GALLIPOT WITH LIP diam. 88 mm	26617	
S/S GALLIPOT WITH LIP diam. 128 mm	26618	
S/S GALLIPOT WITH LIP diam. 158 mm	26619	
S/S GALLIPOT diam.208 mm	26621	
S/S GALLIPOT diam.258 mm	26622	
S/S MEDICINE CUP 60 ml - graduated	26620	802327900Y150915A200010SN
S/S DRESSING JAR 0.5 l with lid - diam.106x66 mm	26623	80232790000V04024300010TJ
S/S DRESSING JAR 1 l with lid - diam.103x128 mm	26624	
S/S DRESSING JAR 2 l with lid - diam.127x162 mm	26625	
S/S FORCEPS JAR - diam. 55x140 mm	26626	80232790000V04024400010TX
S/S FORCEPS JAR - diam. 55x180 mm	26627	
S/S THERMOMETER JAR - diam. 33x80 mm	26628	80232790000V0399C200010CD
S/S INSTRUMENT TRAY - 313X218X31 mm	26629	80232790000V04026400010UZ
S/S ECONOMIC KIDNEY DISH 6" - 162x77x31 mm	26641	80232790000V04020400010RT
S/S ECONOMIC KIDNEY DISH 8" - 207x98x39 mm	26642	
S/S ECONOMIC KIDNEY DISH 10" - 247x122x43 mm	26643	
S/S ECONOMIC KIDNEY DISH 12" - 309x149x59 mm	26644	
S/S PERFORATED INSTRUM. TRAY WITH LID - 223x126x45 mm	26646	80232790000V08996400010BC
S/S PERFORATED INSTRUM. TRAY WITH LID - 355x254x50 mm	26647	
S/S PERFORATED MAYO TRAY - 350x252x16 mm	26651	80232790000V089900000006F
ALUMINIUM BOX - 17.5X7.6X2 cm	26662	80232790000V0499910002087
ALUMINIUM BOX - 18.5X9.5X3 cm	26663	
ALUMINIUM BOX - 21.8X10.6X3 cm	26664	
ALUMINIUM BOX - 21.8X10.6X5 cm	26665	
SWAB HOLDER - 16 cm	26785	802327900L14909900000007B
SCALPEL HANDLE N.3 for blades 10-15	26913	802327900L0101030000000GM
SCALPEL HANDLE N.4 for blades 20-25	26914	
GALLIPOT 90 ml - plastic	37701	80232790000V089916000309P
GALLIPOT 240 ml - plastic	37702	
KIDNEY TRAY 6" 155x75 mm - plastic	37705	80232790000V04020400030RZ
KIDNEY TRAY 8" 205x100 mm - plastic	37706	

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KIDNEY TRAY 10" 260x125 mm - plastic	37707	
KIDNEY TRAY 12" 306x140 mm - plastic	37708	
MEASURING JUG 500 ml - plastic	37710	80232790000V08990900030AD
MEASURING JUG 1000 ml - plastic	37711	
MEASURING JUG 2000 ml - plastic	37712	
LABORATORY TRAY 375x300x75 mm - plastic	37715	80232790000V08996400030BJ
COMPARTMENT TRAY 266x175x42 mm - plastic	37717	
INSTRUMENT TRAY WITH COVER 220x150x70 mm - plastic	37718	
IMPRESSION TRAYS - set of 10 perforated	60040	802327900Q010599000000054
IMPRESSION TRAYS - set of 10 solid	60045	

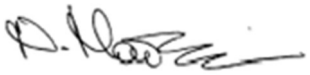
intended purpose: used for a variety of medical purposes, such as collecting fluids, bodily excrements, transporting or containing instruments, intended to be used by specialized healthcare personnel with the function of supporting the medical and/or surgical procedure in the department, clinic or operating room in which they are used

risk class I (not sterile), in accordance with the rule 1 set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the Regulation (EU) 2017/745 (MDR);
- Common Specifications have not been used for the compliance of the above medical device.

Gessate, 25/11/2025

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



S/S DENTAL TRAY - 208X109X15 mm

Product Code	26600
Unit of sale	1 pc
Minimum order	1
Type	Medical device
Class	I

UK-REP	Yes
CH-REP	Yes

RDM (NSIS)	2740226
CND	V0402
EAN/UPC	8023279266009
GMDN	12143

Description

Stainless Steel AISI 304 holloware with minimum thickness 0.6 mm
Dental tray
Size: 208 x 109 x h 15 mm

- Autoclavable 121°C
- AISI 304
- Without cover

S/S INSTRUMENT TRAY - 264X172X47 mm

Product Code	26602
Unit of sale	1 pc
Minimum order	1
Type	Medical device
Class	I

UK-REP	Yes
CH-REP	Yes

RDM (NSIS)	2740258
CND	V0402
EAN/UPC	8023279266023
PARAF	903162473
GMDN	12143

Description

Stainless Steel AISI 304 holloware with minimum thickness 0.6 mm
Instrument tray - round edges - without cover
Size: 264 x 172 x h 47 mm

- Autoclavable 121°C
- AISI 304
- Without cover

S/S INSTRUMENT TRAY - 306X196X50 mm

Product Code	26603
Unit of sale	1 pc
Minimum order	1
Type	Medical device
Class	I

UK-REP	Yes
CH-REP	Yes

RDM (NSIS)	2740258
CND	V0402
EAN/UPC	8023279266030
PARAF	903162485
GMDN	12143

Description

Stainless Steel AISI 304 holloware with minimum thickness 0.6 mm
Instrument tray - angled edges - without cover
Size: 306 x 196 x h 50 mm

- Autoclavable 121°C
- AISI 304
- Without cover

S/S INSTRUMENT TRAY - 440X320X64 mm

Product Code	26598
Unit of sale	1 pc
Minimum order	1
Type	Medical device
Class	I

UK-REP	Yes
CH-REP	Yes

RDM (NSIS)	2740258
CND	V0402
EAN/UPC	8023279265989
GMDN	12143

Description

Stainless Steel AISI 304 holloware with minimum thickness 0.6 mm
Instrument tray - angled edges - without cover
Size: 440 x 320 x h 64 mm

Technical Specifications

- Autoclavable 121°C
- AISI 304
- Without cover