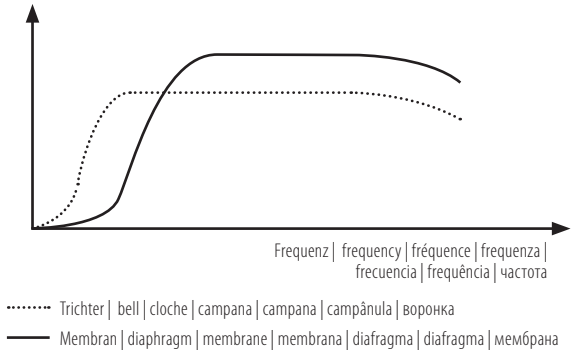

		
Schwestern-Lehr Plano	Petiphon	Pinard klein
		
Schwestern-Lehr Duo	Suprabell (Veterinär)	Pinard groß

		
Profi-Kardiology	Prestige-Standard	Prestige-Standard light
		
Top-Kardiology	Prestige-Child	Prestige-Child light
		
Planet	Prestige-Baby	Prestige-Baby light
		
Planet Air	KaWe COLORSCOP Duo	Double
		
Rapport/Rapport Black-Line	KaWe COLORSCOP Plano	Single

EC-Declaration of Conformity

Document number:	EC-OCNFL-100315	1/4
Manufacturer or representative:	OSRAM China Lighting Co. Ltd	
Address:	No.1 North Industrial Road FoShan, GuangDong, P.R.China	
Brand name or trade mark:	OSRAM	
Product type:	Double-capped fluorescent lamp	
Product designation:		
	☒ See attached list	

The designated product(s) is (are) in conformity with the provisions of the following European Directives.

☒	**2006/95/EC** and amendments	**Directive of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits**
☐	**2004/108/EC** and amendments	**Directive of the European Parliament and of the Council of 15 September 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility**
☐	**2000/55/EC** and amendments	**Directive of the European Parliament and of the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting** (to be repealed by 13 April 2010)
☒	**2009/125/EC** and amendments	**Directive of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products**
☐	**244/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps**
☒	**245/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps ...**

Further information regarding compliance with these Directives is given in the **annex** which constitutes a part of this declaration.

Last two digits of the year in which the CE marking was affixed:

Place and date of signatures:

Signatures:

☒ Plant Manager ☐ Product Manager

Quality Manager

Names and contact addresses:

This declaration certifies compliance with the indicated Directives, but implies no warranty of properties.

EC-Declaration of Conformity
Annex

Document number: 2010/01 FS

The conformity of the designated product(s) with the provisions of the European Directive **2006/95/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 60155:** 1995 + A1:1995 + A2:2007	Glow-starters for fluorescent lamps
☐	**EN 60432-1:** 2000 + A1:2005	Incandescent lamps — Safety specifications — Part 1: Tungsten filament lamps for domestic and similar general lighting purposes
☐	**EN 60432-2:** 2000 + A1:2005	Incandescent lamps — Safety specifications — Part 2: Tungsten filament lamps for domestic and similar general lighting purposes
☐	**EN 60432-3:** 2003 + A1:2005 + A2:2008	Incandescent lamps — Safety specifications — Part 3: Tungsten halogen lamps (non-vehicle)
☐	**EN 60598-1:** 2008	Luminaires — Part 1: General requirements and tests
☐	**EN 60598-2-1:** 1989	Luminaires — Part 2-1: Particular requirements — Fixed general purpose luminaires
☐	**EN 60598-2-2:** 1996 + A1:1997	Luminaires – Part 2-2: Particular requirements — Recessed luminaires
☐	**EN 60598-2-4:** 1997	Luminaires — Part 2-4: Particular requirements — Portable general purpose luminaires
☐	**EN 60598-2-5:** 1998	Luminaires – Part 2-5: Particular requirements — Floodlights
☐	**EN 60598-2-6:** 1994 + A1:1997	Luminaires — Part 2-6: Particular requirements — Luminaires with built-in transformers for filament lamps
☐	**EN 60598-2-7:** 1989 + A2:1996 + A13:1997	Luminaires — Part 2-7: Particular requirements — Portable luminaires for garden use
☐	**EN 60598-2-8:** 1997+ A1:2000 + A2:2008	Luminaires — Part 2-8 : Particular requirements — Handlamps
☐	**EN 60598-2-10:** 2003	Luminaires — Part 2-10: Particular requirements — Portable luminaires for children
☐	**EN 60598-2-13:** 2006	Luminaires — Part 2-13: Particular requirements — Ground recessed luminaires
☐	**EN 60598-2-20:** 1997 + A1:1998 + A2:2004	Luminaires — Part 2: Particular requirements — Lighting chains
☐	**EN 60968:** 1990 + A1:1993 + A2:1999	Self-ballasted lamps for general lighting services — Safety requirements
☒	**EN 61195:** 1999	Double-capped fluorescent lamps — Safety specifications
☐	**EN 61199:** 1999	Single-capped fluorescent lamps — Safety specifications
☐	**EN 61347-1:** 2008	Lamp controlgear — Part 1: General and safety requirements
☐	**EN 61347-2-2:** 2001 + A1:2006 + A2:2006	Lamp controlgear — Part 2-2: Particular requirements for d. c. or a. c. supplied electronic step-down convertors for filament lamps

☐	**EN 61347-2-3:** 2001+A1:2004 + A2:2006	Lamp controlgear — Part 2-3: Particular requirements for a. c. supplied electronic ballasts for fluorescent lamps
☐	**EN 61347-2-12:** 2005	Lamp controlgear — Part 2-12: Particular requirements for d. c. or a. c. supplied electronic ballasts for discharge lamps (excluding fluorescent lamps)
☐	**EN 61347-2-13:** 2007	Lamp controlgear — Part 2-13: Particular requirements for d. c. or a. c. supplied electronic controlgear for LED modules
☐	**EN 61549:** 2003 + A1:2005	Miscellaneous lamps
☐	**EN 62031:** 2008	LED modules for general lighting — Safety specifications
☐	**EN 62035:** 2000 + A1:2003	Discharge lamps (excluding fluorescent lamps) — Safety specifications
☐	**EN 62471:** 2008	Photobiological safety of lamps and lamp systems NOTE: This is a horizontal standard. It is not applicable where photobiological safety is covered by product standards.
☐	**EN 62560:** XXXX	Self-ballasted LED-lamps for general lighting services by voltage > 50 V — Safety specifecations
☒	**IEC 60081:** **1997+A1:2000+A2:2003+A3:2005**	Double-capped fluorescent lamps - Performance specifications
☐		

The conformity of the designated product(s) with the provisions of the European Directive **2004/108/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 55015:** 2006 + A1:2007 + A2:2009	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment
☐	**EN 61000-3-2:** 2006	Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
☐	**EN 61000-3-3:** 1995 + A1:2001 + A2:2005	Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection
☐	**EN 61547:** 1995 + A1:2000	Equipment for general lighting purposes — EMC immunity requirements
☐		

The conformity of the designated product(s) with the provisions of the European Directive **2000/55/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 50294:** 1998	Measurement method of total input power of ballast-lamp circuits

EC-Declaration of Conformity
Attached list

Document number: EC-OCNFL-100315

A61924700DC	HNS 15W G13 20X1	OSRAM
A61926100DC	HNS 30W G13 10X1	OSRAM

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

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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)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0004

CISQ
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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.

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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

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IT-149833 ICIM-13485-050862-02

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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

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The International Certification Network
www.iqnet-certification.com

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

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 / *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.

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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
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MS N° 0004

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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.

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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*:
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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.
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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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ITALIAN DIVISION
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EXPORT DIVISION
export@gimaitaly.com

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 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 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	
KIDNEY TRAY 10" 260x125 mm - plastic	37707	
KIDNEY TRAY 12" 306x140 mm - plastic	37708	
MEASURING JUG 500 ml - plastic	37710	80232790000V08990900030AD

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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	

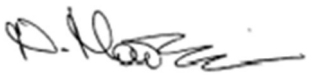
intended purpose: used for a variety of medical purposes, such as collecting fluids, bodily excrements, transporting or containing instruments, intended to be used by specialized healthcare personnel with the function of supporting the medical and/or surgical procedure in the department, clinic or operating 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, 15/04/2025

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



Microscope Slide

Microscope Slide

Slide with 90° Corner, 45° Clipped Corner, both beveled edges and clipped corners.
50pcs/box and 72pcs/box are available.

Cat. No.	Description	Dim. (mm)	Thickness (mm)	Qty/Case
7101	Ground Edges	25.4×76.2 (1''×3'')	1-1.2	50
7102	Cut Edges	25.4×76.2 (1''×3'')	1-1.2	50
7103	Single Cavity, Ground Edges	25.4×76.2 (1''×3'')	1-1.2	50
7104	Double Cavities, Ground Edges	25.4×76.2 (1''×3'')	1-1.2	50
7105	Ground Edges, Frosted One End One Side	25.4×76.2 (1''×3'')	1-1.2	50
7105-1	Cut Edges, Frosted One End One Side	25.4×76.2 (1''×3'')	1-1.2	50
7106	Ground Edges, Frosted Two Ends One Side	25.4×76.2 (1''×3'')	1-1.2	50
7107	Ground Edges, Frosted One End Both Sides	25.4×76.2 (1''×3'')	1-1.2	50
7107-1	Cut Edges, Frosted One End Both Sides	25.4×76.2 (1''×3'')	1-1.2	50
7109	Ground Edges, Color Frosted One End One Side, White, Orange, Yellow, Green, Pink, Blue	25.4×76.2 (1''×3'')	1-1.2	50

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DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

La Società GIMA S.P.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/*Ref. #***
PULSOXIMETRO DA DITO OXY – PEDIATRICO / *FINGER PULSE OXIMETER OXY - PAEDIATRIC*	34266
PULSOXIMETRO DA DITO OXY-5 PLUS / *FINGER PULSE OXIMETER OXY-5 PLUS*	34282
PULSOXIMETRO DA DITO OXY-6 / *FINGER PULSE OXIMETER OXY-6*	34285
PULSOXIMETRO DA POLSO / *WRIST PULSE OXIMETER*	34340
PULSOXIMETRO OXY-100 / *PULSE OXIMETER OXY-100*	34342
PULSOXIMETRO OXY-5 PEDIATRICO / *PULSE OXIMETER OXY-5 - PAEDIATRIC*	34265
PULSOXIMETRO OXY-3 / *PULSE OXIMETER OXY-3*	35090
PULSOXIMETRO OXY-50 / *PULSE OXIMETER OXY-50*	35100
PULSOXIMETRO OXY-4 – colore a scelta / *PULSE OXIMETER OXY-4 - any colour*	35093
PULSOXIMETRO OXY-10 / *PULSE OXIMETER OXY-10*	35095
PULSOXIMETRO OXY-4 BLU / *PULSE OXIMETER OXY-4 BLUE*	35091
PULSOXIMETRO OXY-4 ARANCIONE / *PULSE OXIMETER OXY-4 ORANGE*	35092

appartenente alla classe di rischio IIa in accordo alla regola 10 dell'Allegato IX, della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class IIa, according to rule 10 of the Annex IX, Directive 93/42/EEC and subsequent amendments and integrations (enforced in Italy by Leg. Decree No. 46/97 and subsequent amendments and integrations), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and subsequent amendments and integrations, as per the Technical Documentation filed in the Company;
- sono fabbricati in accordo al Sistema Qualità, che soddisfa i requisiti di cui all'Allegato V del sopra citato decreto legislativo, come risulta dal Certificato n. MED 26036 rilasciato in data 25/10/2006 dal KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Organismo Notificato n. 0476;
  are manufactured according to the Quality System which satisfies requirements of the Annex V of the above mentioned directive, as stated in the Certificate No. MED 26036 issued on 25/10/2006 by KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Notified Body n. 0476;
- sono conformi alla direttiva 2011/65/UE e ss.mm.ii. del Parlamento europeo e del Consiglio dell'8 giugno 2011, sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.

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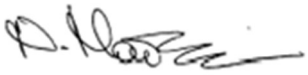
comply with Directive 2011/65/EU and subsequent amendments and integrations of the European Parliament and of the Council of 8 June 2011 on the restriction of certain hazardous substances in electrical and electronic equipment.

Gessate, 24/05/2021

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



БАКТЕРИЦИДНАЯ ГАЗОРАЗРЯДНАЯ ЛАМПА НИЗКОГО ДАВЛЕНИЯ

(TUV-30 TUV-15 TUV-8)

F30 TB G13 F15 TB G13 F8 TB G13

ИНСТРУКЦИЯ ПО ЭКСПЛУАТАЦИИ

1. ВВЕДЕНИЕ

1.1. Настоящая инструкция определяет правила установки, эксплуатации, хранения и транспортирования ламп ртутных низкого давления для облучателей бактерицидных медицинских, в дальнейшем именуемых «лампы». Оболочка ламп выполнена из стекла, хорошо пропускающего излучение с длиной волны 253,7 нм, обладающего наибольшим бактерицидным действием. Стекло отфильтровывает 185-нм линию спектра, ответственную за образование озона.

Бактерицидные лампы низкого давления (арт. F30 TB G13 F15 TB G13 F8 TB G13) являются не образующими озон при работе соответствуют требованиям безопасности стандарта ГОСТ 12.2.007.13-2000

1.2. В условном обозначении ламп буквы и цифры обозначают:

- Р – дуговая бактерицидная;
- 8,15,30 – номинальная мощность в Вт;
- G13 – тип цоколя;
- ТВ – тип колбы лампы;

2. ОБЩИЕ УКАЗАНИЯ

2.1. Лампы предназначены для использования в медицине для обеззараживания воздуха помещений лечебных учреждений, бактериологических лабораторий, станций переливания крови, детских учреждений, а также цехов промышленных предприятий, для обеззараживания предметов обихода, питьевой и минеральной воды, обеззараживания и предохранения от микробного загрязнения пищевых продуктов, оборудования и тары в пищевой промышленности и других аналогичных целей.

2.2. Лампы питаются от сети переменного тока частоты 50 Гц напряжением 220 В с соответствующей пускорегулирующей аппаратурой по ГОСТ 16809 в схемах стартерного зажигания.

2.3. Общий вид ламп и основные размеры приведены на рис. 1 и в таблице 1.

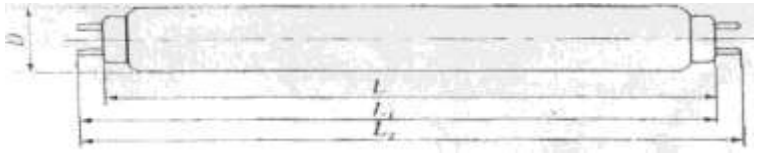


Таблица 1

2.4. Основные параметры ламп приведены в таблице 2

Тип лампы	L мм. min -max	L_1 мм. min -max	L_2 мм. min -max	D мм.	Всего нетто гр.	Тип цоколя
F8	287	295	302	15	24	G13
F15	437,4	443.1-445.5	451.6	26.5	75	G13
F30	894,6	899.3-901.7	908.8	26.5	140	G13

Таблица 2

Тип лампы	Мощность Вт.	Напряжение на лампе, В	Сила тока, А.	Лучистый поток		срок горения, ч
				Номин.	Не менее	
F8	8	56	0,15	2,1	1,58	6000
F15	15	54	0,310	3,8	3,3	6000
F30	30	104	0,365	9,0	8,0	6000

2.5. Спад светового потока после средней продолжительности горения должен составлять не менее 75 % номинального значения

3. МЕРЫ БЕЗОПАСНОСТИ

3.1. При работе с бактерицидной лампой, находящейся в поле зрения, необходимо защищать глаза очками с простыми стёклами и иметь в виду, что облучение бактерицидной лампой при отсутствии защитных средств может вызвать болезненный ожог кожи лица, рук, а также слизистых оболочек глаз.

3.2. Лампы, как и вес приборы, имеющие оболочку из стекла, гребуют аккуратного обращения.

Лампы необходимо предохранять от ударов, резких сотрясений, * падений, резких колебаний температуры.

3.3. Производить смену ламп, очистку от пыли при отключенной питающей сети облучательной установки.

3.4. Вследствие токсичности ртути, если лампа разбилась, необходимо тщательно собрать ее остатки, немедленно вынести их за пределы помещения, а место, где разбилась лампа, промыть однопроцентным раствором марганцево-кислого калия.

3.5. Вышедшие из строя лампы должны храниться упакованными в специальном помещении и периодически вывозиться в специально отведенное место.

3.6. До вывоза ламп на место сваливания хозяйственно-бытовых и промышленных отбросов содержащаяся в лампах ртуть должна быть изъята либо нейтрализована. Вскрытие отработанных ламп и удаление из них ртути рекомендуется производить в вытяжных шкафах, оснащенных фильтрами- поглотителями паров ртути с самостоятельной вентиляцией. Очистка ламп должна производиться в глубоких эмалированных противнях.

После возможно более полного механического удаления металлической ртути необходимо поместить колбы ламп на несколько часов в растворы химических демеркуризаторов, которыми являются: 10— 15% водный раствор азотной кислоты, 20% раствор хлорного железа и раствор йода в водном растворе йодистого калия (2,5 г йода и 30 г йодида калия и 1 л воды). Отработанные растворы можно сливать в канализацию.

Указания относительно строительных конструкций помещений, в которых должно производиться извлечение ртути, их вентиляция и т. д., имеются в «Санитарных правилах проектирования оборудования, эксплуатации и содержания производственных и лабораторных помещений, предназначенных для проведения работ со ртутью, ее основными соединениями и приборами со ртутным наполнением».

4. ПОРЯДОК УСТАНОВКИ ЛАМП

4.1. Лампы изготовляются исполнения УХЛ категории 4.2 по ГОСТ 15150 для работы в следующих условиях:

- положение лампы во время горения—любое;
- температура окружающего воздуха от + 10°С до +55°С;
- относительная влажность воздуха не более 70% при 25°С;
- высота над уровнем моря не более 2000 м;
- окружающая среда не должна быть взрывоопасной, насыщенной токо-проводящей пылью и химически активной;
- отсутствие тряски, виорации, ударов.

4.2. Включение ламп в электрическую сеть производится по схеме, приведённом н

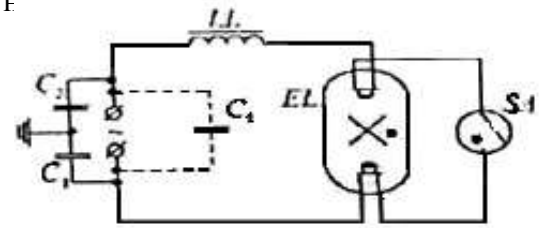


Рис. 2.

EL – Включение ламп в электрическую сеть производится по схеме

SA – стартер;

LL – пускорегулирующий аппарат;

C_1 – компенсирующий конденсатор емкостью 4—6 мкф;

C_2; C_3 – конденсатор ограничения радиопомех емкостью 0,5 мкф.

4.3. Наиболее эффективный режим работы ламп наступает через 15 минут после включения при температуре окружающей среды от +18 до 27 С.

4.4. Понижение или повышение напряжения относительно номинального отрицательно сказывается на работе ламп.

При напряжении менее 180 В лампы не зажигаются, при повышенном напряжении быстро разрушаются электроды и сокращается срок службы ламп.

5. ХРАНЕНИЕ И ТРАНСПОРТИРОВАНИЕ

5.1. Храниться лампы должны в упаковке в закрытом, сухом, проветриваемом помещении при отсутствии в воздухе паров кислот и щелочей. При хранении ламп температура окружающего воздуха должна быть не ниже плюс 5°С и не выше плюс 40°С. Относительная влажность воздуха — не более 80% при температуре окружающей среды 20°С и при более низких температурах без конденсации влаги.

Срок хранения 2 года