

Anexa 6 Fotoliu recoltarea singelui

Caracteristici solicitate	Caracteristici oferite 27557, Gima
Fotoliu pentru recoltarea sîngelui Descriere Destinat amplasării pacientului pentru recoltarea sîngelui Parametrul Specificația Acțiune mecanică, electromecanică Secțiuni ≥ 3 Suporturi pentru mîini Înălțimea suportului pentru mîini reglabilă, 70-95cm $\pm 10\%$ Carcasul oțel vopsit electrostatic Suprafața acoperită cu material moale, rezistent la detergenți chimici Capacitate maximă ≥ 150 kg	Fotoliu pentru recoltarea sîngelui Descriere Destinat amplasării pacientului pentru recoltarea sîngelui Parametrul Specificația Acțiune mecanică, electromecanică Secțiuni ≥ 3 Suporturi pentru mîini Înălțimea suportului pentru mîini reglabilă, 70-95cm $\pm 10\%$ Carcasul oțel vopsit electrostatic Suprafața acoperită cu material moale, rezistent la detergenți chimici Capacitate maximă ≥ 150 kg

Anexa 12 Lampă pentru examinare, brat flexibil (caracteristici de baza)

Caracteristici solicitate	Caracteristici oferite 30759,Gima
Lampă pentru examinare, braț flexibil (caracteristici de baza) Cod 130100 Descriere Lampă de examinare cu braț flexibil pe suport mobil Alimentare 220V, 50Hz. Dimensiunea câmpului luminous ≥ 120 mm Temperatura culorii 4000 - 5500 K Cu înălțime reglabilă 1500-1800 mm (diapazon) Suport cu acoperire anticorozivă reglabil pe verticala Baza cu acoperire anticorozivă Tehnologia Iluminarea bazată pe tehnologia LED Timpul de viață a LED-urilor $\geq 50\,000$ h Braț flexibil da Nivelul de iluminare la distanță de 50 cm minim 35 000 lux Mobil pe suport cu minim 5 roți da	Lampă pentru examinare, braț flexibil (caracteristici de baza) Cod 130100 Descriere Lampă de examinare cu braț flexibil pe suport mobil Alimentare 220V, 50Hz. Dimensiunea câmpului luminous la 50 cm – d.140 mm Temperatura culorii la 1 m - 4200K Cu brat flexibil reglabil Suport cu acoperire anticorozivă Baza cu acoperire anticorozivă Tehnologia Iluminarea bazată pe tehnologia LED Timpul de viață a LED-urilor $\geq 50\,000$ h Braț flexibil da Nivelul de iluminare la distanță de 50 cm minim 35 000 lux Mobil pe suport cu minim 5 roți da



GIMA

SIMPLEX LED LIGHT - trolley

Code:	30759
Category:	Diagnostic, examination lights
Unit of sale:	1 pc.
Minimum order:	1
Type:	Medical device
Class:	I
NSIS:	969078
CND:	Z129004
EAN13:	8023279307597

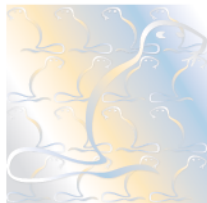


Description: Thanks to 3 independent light sources shadow can be reduced and provide a deep cylindrical light with highly reduced heat irradiation. Each LED integrates a resistance to ensure the continuous operation of the lamp even in the rare case of a LED fault. Other specifications as halogen model. Made in Italy.

The flexible arm (60 cm) ensures easier light positioning and is covered with a smooth white shrink-wrap sheath for easier cleaning and disinfection.

Technical Specifications:

- Type of lighting: LED
- Consumption (Watt): 3x1.4
- Life of the bulbs (hours): > 50,000
- Light intensity at 50 (lux): > 35,000
- Light intensity at 1 m (lux): 13,000
- Colour temperature at 5% at 1 m (K): 4,200
- Colour rendering index (Ra)%: -
- Light field size at 50 cm (Ø mm): 140
- External Ø of the reflector (mm): 86
- Colour: white
- Norms: IEC 60601-1
- Marks: CE 93/42
- Weight (kg): 5
- Operating voltage V: 100-230
- Operating Hz: 50/60



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		

Previous expiry date

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 manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

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

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

This certificate is composed of 1 page.

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EU DECLARATION OF CONFORMITY

In accordance with Article 19 and Annex IV of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturer: **RIMSA P. LONGONI S.r.l.**

Address of registered place of business: Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) – ITALY

Single registration number (SRN): not yet issued by the competent authority

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device identification: LUMINAIRE FOR DIAGNOSIS

Basic UDI-DI	Device code	Device name
++B880ALFAFIXSJ	ALFA-FIX	LAMP MODEL ALFA-FIX
++B880ALFAFLEXV7	ALFA-FLEX	LAMP MODEL ALFA-FLEX
++B880L88LEDMMMA	L88-LED-M	LAMP MODEL L88-LED MEDICAL
++B880PRIMAFIXD3	PRIMA-FIX	LAMP MODEL PRIMALED JOINTS ARM
++B880PRIMAFLEXMA	PRIMA-FLEX	LAMP MODEL PRIMALED-FLEX

Risk class of the device in accordance with the rules set out in Annex VIII of REGULATION (EU) 2017/745: **CLASS I**

Explanation: Duration: Short term (Annex VIII, CHAPTER I, point 1. DURATION OF USE)

Description: Non-invasive medical device (Annex VIII, CHAPTER III, point 4. NON-INVASIVE DEVICES, par. 4.1 Rule 1)

Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, par. 6.2 Rule 10)

The manufacturer declares that the medical device is in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and with the following standards:

- IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
- IEC 60601-1-2 (Part 2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)
- IEC 60601-2-41 (Part 1: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis)

The conformity assessment procedure is developed with reference to premise (60) and Article 52 of REGULATION (EU) 2017/745.

RIMSA Quality System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).

Seregno, 26/05/2021

Place and date

Mark and sign of Managing Director
(Paolo Longoni)



GIMA

DONOR ARMCHAIR - mechanical - blue

Code: 27557

Category: Electrical and mechanical chairs

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: I

NSIS: 1554792

CND: V0802

EAN13: 8023279275575



Description: DONOR ARMCHAIR - blue - mechanical

Strong and stylish armchair with structure made of oval, round and square metal tubing fully coated with white epoxy powder (legs oval tubing 50 x 25 x 1.5 cm; central frame square tubing 30 x 30 x 1.5 cm, cushions round tubing 20 x Ø 1.5 cm).

High density polyurethane foam platform with wooden base covered by leatherette upholstery. Flame resistant Class 1 IM.

Synchronized adjustment of the two cushions by a gas spring, cylinder/piston.

Backrest inclination from +60° to -5° in Trendelenburg position, leg rest from -80° to +5°.

Reclinable arm-rests can be height adjusted and rotated up to 180° When removed.

Four adjustable feet ensure maximum stability.

Load: 150 kg.

Size: 175 x 55 x h 51 cm.

Made in Italy.