Anexa nr.6 Lampa de examinare, brat flexibi (caracteristici de baza)				
Descriere			Lampa de examinare, brat flexibi (caracteristici de baza),cod:130100	
Parametrul			**Specificația solicitata**	**Specificatia tehnica oferita 49040 (Gima/Italia)**
Alimentare			220V,50Hz	110-264V,50/60Hz
Dimensiunile cimpului iluminos			≥120 mm	120 mm la distanta de 50 cm si 180mm la distanta de 100cm
Temperatura culorii			4000-5500 K	4800-5500 K
Cu inaltime reglabila			1500--1800 mm diapazon	1500--1800 mm diapazon
Suport	**cu acoperire anticoroziva**		cu acoperire anticoroziva	cu acoperire anticoroziva
	Reglabil pe verticala		da	da
Baza	**cu acoperire anticoroziva**		da	da
	Minim 5 roti		da	da
Tehnologia		**Iluminarea bazata pe tehnologia**	LED	LED
Timpul de viata a LED-urilor			≥ 50000h	da
Brat flexibil			da	da
Nivel de iluminare la 50 cm distanta			35 000 lux	65 000 lux
Mobil pe suport cu minim 5 roti			da	da

Digitally signed by Ceaicovschi Tudor
Date: 2021.07.01 10:43:32 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr.19 Targa sanitara, cod 140360		
Descriere	Dispozitiv medical utilizat pentru transportul pacientilor, in cadrul departamentului de urgenta	
Parametrul	**Specificația solicitata**	**Specificatia tehnica oferita 34077 (Gima/Italia)**
Tip	pliabila	pliabila
Fixare pacient	da	da
Tetieră reglabila	da	da
Material Bară de transport	Oțel inox/Al Acoperire stofă reziztentă lavabilă	Oțel inox/Al Acoperire stofă reziztentă lavabilă
Sarcina maximă	≥150 kg	150 kg
Dimensiuni in stare intinsa	≤209 x 60 x 15 cm	188 x 53 x 21cm
Dimensiuni in stare pliata	≤98 x 60 x 20 cm	92 x 53 x 12cm
Cadru de metal cu minim 3 bare transversale Să se atribuie dimensiunilor constructive	da	da

CERTIFICATE

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.

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

SGQ N° 007A

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

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

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

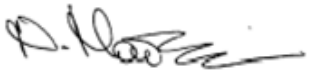
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
HYRIDIA 7 LEDS LIGHT with flexible arm - trolley	49040	8023279Z120107020000000RC

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

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



HYRIDIA 7 LEDS LIGHT with flexible arm - trolley

Code:	**49040**
Category:	**Diagnostic, examination lights**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1860820**
CND:	**Z12010702**
EAN13:	**8023279490404**

Description:

HYRIDIA 7 LEDS LIGHT - flexible arm - trolley

7 leds 10W medical procedure lights on trolley with flexible soft arm or metal spring arm.

Digital brightness control.

Manual: GB, FR, IT, ES, PT, DE, PL, GR.

Handle on the lamphead.
Metal steering head makes direction more flexible.
360° Free position flexible metal arm, 76 cm length.
Detachable large base with brake.

Technical Specifications:

- Consumption: 10 W
- Colour temperature: 4,800-5,500 °K
- External Ø of reflector: 89 mm
- Colour rendering index (CRI): 75 ra
- Operating voltage: 110-265 V, 50/60 Hz
- Light intensity and light field Ø:
illumination 78,000 lux / Ø 9 cm / distance 30 cm
illumination 65,000 lux / Ø 12 cm / distance 50 cm
illumination 22,000 lux / Ø 18 cm / distance 100 cm

WHEEL STRETCHER

Code:	**34077**
Category:	**Foldable stretchers**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1133759**
CND:	**V0899**
EAN13:	**8023279340778**

Description:

WHEEL STRETCHER - foldable in 2

Wheels, outriggers and adjustable backrest. High strength aluminium poles and vinyl coated, waterproof nylon canvas.
Light weight, small sized, easy to carry.

Technical Specifications:

- **Open size: 188 x 53 x 21 cm**
- **Folded size: 92 x 53 x 12 cm**
- **Weight: 8 kg**
- **Load: 150 kg**

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

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

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
WHEEL STRETCHER	34077	80232790000V089906000008V

Risk class I (Not sterile), according to the Rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

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