

Anexa 52 Negatoscop, Cod 210700

Specificatia tehnica solicitata	Specificatia tehnica ofertata, Model 27358 (Gima, Italia)
Negatoscop, Cod 210700 Descriere Dispozitiv destinat pentru vizualizarea filmelor radiografice sau tomografice Parametru Specificație Nr. de cadre ≥ 2 Nr. de lampe ≥ 2 Reglare luminozitate da Fixarea filmelor da Fixare masă/perete Ecran anti-glare da Alimentare 220V, 50Hz	Negatoscop, Cod 210700 Descriere Dispozitiv destinat pentru vizualizarea filmelor radiografice sau tomografice Parametru Specificație Nr. de cadre -2 Nr. de lampe -2 Reglare luminozitate da Fixarea filmelor da Fixare masă/perete- da Ecran anti-glare da Alimentare 220V, 50Hz

DECLARATION OF CONFORMITY



BIEFFE ITALIA s.r.l.

Annex VII Directive 93/42/CEE and further modifications and integrations

Declares under its responsibility that the products:

Standard VIEWER

codes

BFAL 43.43 OR; BFL 43.70 OR/VE/OV; BFAL 43.90 OR/VE/OV;
BFAL 43.120 OR/VE/OV; BFAL 43.150 OR/VE/OV;
BFAL 86.120 OR; BFAL 86.150 OR

Luminous OPTOTYPE

Codes

BFAL 27.67 AL; BFAL 27.67 BL; BFAL 27.67 CL; BFAL
27.67 DL; BFAL 27.67 EL; BFAL 27.67FBL

Non luminous OPTOTYPE

Codes

BFAL 27.67 A; BFAL 27.67 B; BFAL 27.67 C; BFAL 27.67 D;
BFAL 27.67 E; BFAL 27.67 F

are in conformity with:

- the essential requirements of the EEC Directive 93/42/CEE and
further modifications and integrations as Class I medical device

Carinaro, June 2018

BIEFFE ITALIA s.r.l.
Dr. Flavio Ferrazzano
CEO

Rev.02

DICHIARAZIONE DI CONFORMITA'



BIEFFE ITALIA s.r.l.

Allegato VII della Direttiva 93/42 /CEE e ulteriori modifiche e integrazioni

Dichiara, sotto la propria responsabilità, che i prodotti:

NEGATIVOSCOPIO standard

Codici

BFAL 43.43 OR; BFL 43.70 OR/VE/OV; BFAL 43.90 OR/VE/OV;
BFAL 43.120 OR/VE/OV; BFAL 43.150 OR/VE/OV;
BFAL 86.120 OR; BFAL 86.150 OR

OTTOTIPO luminoso

Codici

BFAL 27.67 AL; BFAL 27.67 BL; BFAL 27.67 CL; BFAL 27.67 DL;
BFAL 27.67 EL; BFAL 27.67FBL

OTTOTIPO non luminoso

Codici

BFAL 27.67 A; BFAL 27.67 B; BFAL 27.67 C; BFAL 27.67 D;
BFAL 27.67 E; BFAL 27.67 F

sono conformi:

ai requisiti previsti dalla **Direttiva 93/42/CEE** e successive modifiche ed integrazioni relativi ai dispositivi medici in qualità di Dispositivo Medico Classe I

Carinaro, Giugno 2018

BIEFFE ITALIA s.r.l

Dr. Flavio Ferrazzano

Amministratore Unico



GIMA

LIGHT BOX 38x 92 cm - double

Code: 27366
Category: Standard light boxes
Unit of sale: 1 pc.
Minimum order: 1
Type: Medical device
Class: I
NSIS: 102557
CND: Z110702
EAN13: 8023279273663



Description: GIMA light boxes are designed according to clinical standards for an extra white light for an accurate and precise reading of any detail.

• External dimensions

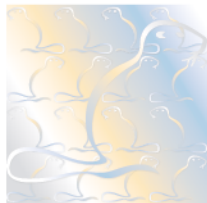
- Length: 97 cm
- Height: 43 cm
- Depth: 12 cm
- Weight: 11 kg
- 2 panels

Incorporates a 3 mm acrylic screen compliant with safety norms (fuses, Schuko plug, green light On/Off, ...).

Can be used on the table placed horizontally, vertically, depending on model or wall mounted.

Body made of oven-fired epoxy powder coated aluminium and injected ABS (colour RAL 7035).

Technical Specifications: Color temperature: cold white 6,500 ° K
Power supply: 230 V - 50 Hz (60 Hz available with surcharge)
Protection fuse: 2x1A
Bipolar switch
Plug: Schuko with 2 meters cable
UL, DVE, IMQ approved components
Made in Italy



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.
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CERMET

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