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

Digitally signed by Ceaicovschi Tudor
Date: 2021.07.08 11:25:31 EEST
Reason: MoldSign Signature
Location: Moldova

BIEFFE ITALIA s.r.l. weiko®
Sede legale: Viale Lincoln, 178 - 81100 Caserta (Italy)
Stabilimento: Consorzio Siné
Zona ASI Aversa Nord 81032 Carinaro (CE)
Tel: +39 081 8654662 Fax: +39 081 8654723
bieffeita@libero.it - www.weiko.com

C.C.I.A.A. 147379
Trib. S. Maria C.V. 16412
P. IVA 02220390617

Bank:
CARIPARMA c/c 000056503302
ABI 06230 CAB 14910 CIN E
IBAN IT75 E 06230 14 910 000056503302
BIC Swift CRP PIT 2P

DECLARATION OF CONFORMITY

CE

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'

CE

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

Rev.02

BIEFFE ITALIA s.r.l. *weiko*®
Sede legale: Viale Lincoln, 178 - 81100 Caserta (Italy)
Stabilimento: Consorzio Siné
Zona ASI Aversa Nord 81032 Carinaro (CE)
Tel: +39 081 8654662 Fax: +39 081 8654723
bieffeita@libero.it - www.weiko.com

C.C.I.A.A. 147379
Trib. S. Maria C.V. 16412
P. IVA 02220390617

Coordinate Bancarie:
CARIPARMA c/c 000056503302
ABI 06230 CAB 14910 CIN E
IBAN IT75 E 062 30 14 910 000056503302
BIC Swift CRP PIT 2P

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
- Lenght: 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

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