

DECLARATION OF CONFORMITY



Annex IV - 745/2017 MDR

BIEFFE ITALIA S.r.l.

As manufacturer of the products underneath listed, declare under its own responsibility that the products:

BF LED 50.1 - BF LED 50.2 - BF LED 50.3
BF LED 50.4 - BF LED 50.1 F - BF LED 50.2 F
BF LED 50.3 F - BF LED 50.4 F - BF LED 50.1 F I
BF LED 50.2 F I - BF LED 50.3 F I - BF LED 50.4 F I
BF LED 50.1 F T1 - BF LED 50.1 F T2 - BF LED 50.1 F T3

leading to the product family:

SLIM LED VIEWER

BASIC UDI-DI: 805373671LED50.XBP

are in conformity

with the essential requirements of the **745/2017 MDR** as Class I medical devices according to Annex VIII, Chapter III, Rule 1 (one).

Carinaro, 13 May 2021

BIEFFE ITALIA S.r.l.

Dr. Flavio Ferrazzano

CEO



GIMA

ULTRA SLIM LED LIGHT BOX 42x72 cm - double

Code: 44701
Category: Ultraslim light boxes
Unit of sale: 1 pc.
Minimum order: 1
Type: Medical device
Class: I
NSIS: 1040746
CND: Z110702
EAN13: 8023279447019



Description: WALL LED SLIM VIEWER 42 x 72 cm

- External size
 - Length: 82 cm
 - Height: 50,5 cm
 - Depth: 3.8 cm
- Weight: 8 Kg
- Switches: 1
- Types: 2 pannels

LED TECHNOLOGY SLIM X-RAY ILLUMINATORS

The new generation of LED X-ray illuminators with colour temperature of 7,200°K for superior viewing and reading of radiography.

Complete elimination of light flickering and 5.000 cd/mq luminance for more uniform light diffusion.

Frame in antiscratch anodized aluminium.

Film gripping system incorporated.

Dimmer for luminance adjustment from 30% to 100%.

- FAS: automatic switching on/off at the positioning/removal of the film.

Economic advantages:

- LED life 80,000 hours, with low maintenance costs
- low energy consumption compliant with European law

Double support for horizontal or vertical wall mounting or desktop.

Technical Specifications:

- Colour temperature: Cool white 7200°K
- Brightness: 5000 cd/m2
- LED life: 80000 hours
- Power supply: 110-230V - 50/60 Hz
- Conformity to Low Voltage Directive 2014/35/CE
- Conformity to Electro Magnetic compatibility 2014/30/CE
- Conformity to EEC directive 2007/47 medical Device Class I
- All components UL, DVE, IMQ approved
- Made in Italy



DICHIARAZIONE CONFORMITA' RoHS 2

BIEFFE ITALIA S.r.l.

dichiara

che i tutti i dispositivi elettromedicali di sua produzione sono conformi alla Direttiva 2011/65/CE (RoHS 2) riguardante la restrizione dell'uso delle seguenti sostanze nelle apparecchiature elettriche ed elettroniche:

Piombo

Mercurio

Cadmio

Cromo esavalente

Bifenili polibromurato (PBB)

Eteri di difenile polibromurato (PBDE)

BIEFFE ITALIA srl

Dr. Flavio Ferrazzano

Amministratore Unico



Reg. Number	1042 - A	Valid From	2021-11-16
First issue date	1999-08-03	Last change date	2021-11-16
Valid Until	2024-12-14	IAF Sector	19, 17

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

BIEFFE ITALIA S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design and manufacturing of electromedical equipment under the Weiko brand:

Medical equipment trolleys, Trolleys for the computerized management of diagnostic and therapeutical procedures, Diagnostic images visualization equipment, Optometric equipment.

Chief Operating Officer
Giampiero Belcredi

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

BIEFFE ITALIA S.r.l.

Registered Headquarters

- Viale Lincoln 178 81100 Caserta Italia

Certified Sites

- Viale Lincoln 178 81100 Caserta Italia - Zona ASI - Aversa Nord 81032 CARINARO (CE) Italia



Reg. Numero	1042 - A	Valido da	2021-11-16
Primo rilascio	1999-08-03	Ultima modifica	2021-11-16
Scadenza	2024-12-14	Settore IAF	19, 17

Certificato del Sistema di Gestione per la Qualità **ISO 9001:2015**

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:

BIEFFE ITALIA S.r.l.

è conforme alla norma UNI EN ISO 9001:2015 per i seguenti prodotti/servizi:

Progettazione e produzione di apparecchiature elettromedicali a marchio Weiko:

Carrelli per supporto e movimentazione di Dispositivi Medici, Carrelli per la gestione informatizzata di procedure diagnostiche e terapeutiche, Apparecchiature per la visualizzazione di immagini diagnostiche, Ausili per optometria.

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Il presente certificato è costituito da 1 pagina.

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

CERMET

BIEFFE ITALIA S.r.l.

Sede Legale

- Viale Lincoln 178 81100 Caserta Italia

Sedi Oggetto di Certificazione

- Viale Lincoln 178 81100 Caserta Italia - Zona ASI - Aversa Nord 81032 CARINARO (CE) Italia





Reg. Number	1042 - M	Valid From	2021-11-16
First issue date	1999-08-03	Last change date	2021-11-16
Valid until	2024-12-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

BIEFFE ITALIA S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and manufacturing of electromedical equipment under the Weiko brand:
Medical equipment trolleys, Trolleys for the computerized management of diagnostic and therapeutical procedures, Diagnostic images visualization equipment, Optometric equipment.

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.

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

CERMET

BIEFFE ITALIA S.r.l.

Registered Headquarters

- Viale Lincoln 178 81100 Caserta Italia

Certified Sites

- Viale Lincoln 178 81100 Caserta Italia - Zona ASI - Aversa Nord 81032 CARINARO (CE) Italia





Reg. Numero	1042 - M	Valido da:	2021-11-16
Primo rilascio	1999-08-03	Ultima modifica	2021-11-16
Scadenza	2024-12-14		

Certificato del Sistema di Gestione per la Qualità

ISO 13485:2016

Si dichiara che il Sistema di Gestione per la Qualità dell'Organizzazione:

BIEFFE ITALIA S.r.l.

è conforme alla norma UNI CEI EN ISO 13485:2016 per i seguenti prodotti/servizi:

Progettazione e produzione di apparecchiature elettromedicali a marchio Weiko:
Carrelli per supporto e movimentazione di Dispositivi Medici, Carrelli per la gestione informatizzata di procedure diagnostiche e terapeutiche, Apparecchiature per la visualizzazione di immagini diagnostiche, Ausili per optometria.

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Il presente certificato è costituito da 1 pagina.

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

CERMET

BIEFFE ITALIA S.r.l.

Sede Legale

- Viale Lincoln 178 81100 Caserta Italia

Sedi Oggetto di Certificazione

- Viale Lincoln 178 81100 Caserta Italia - Zona ASI - Aversa Nord 81032 CARINARO (CE) Italia



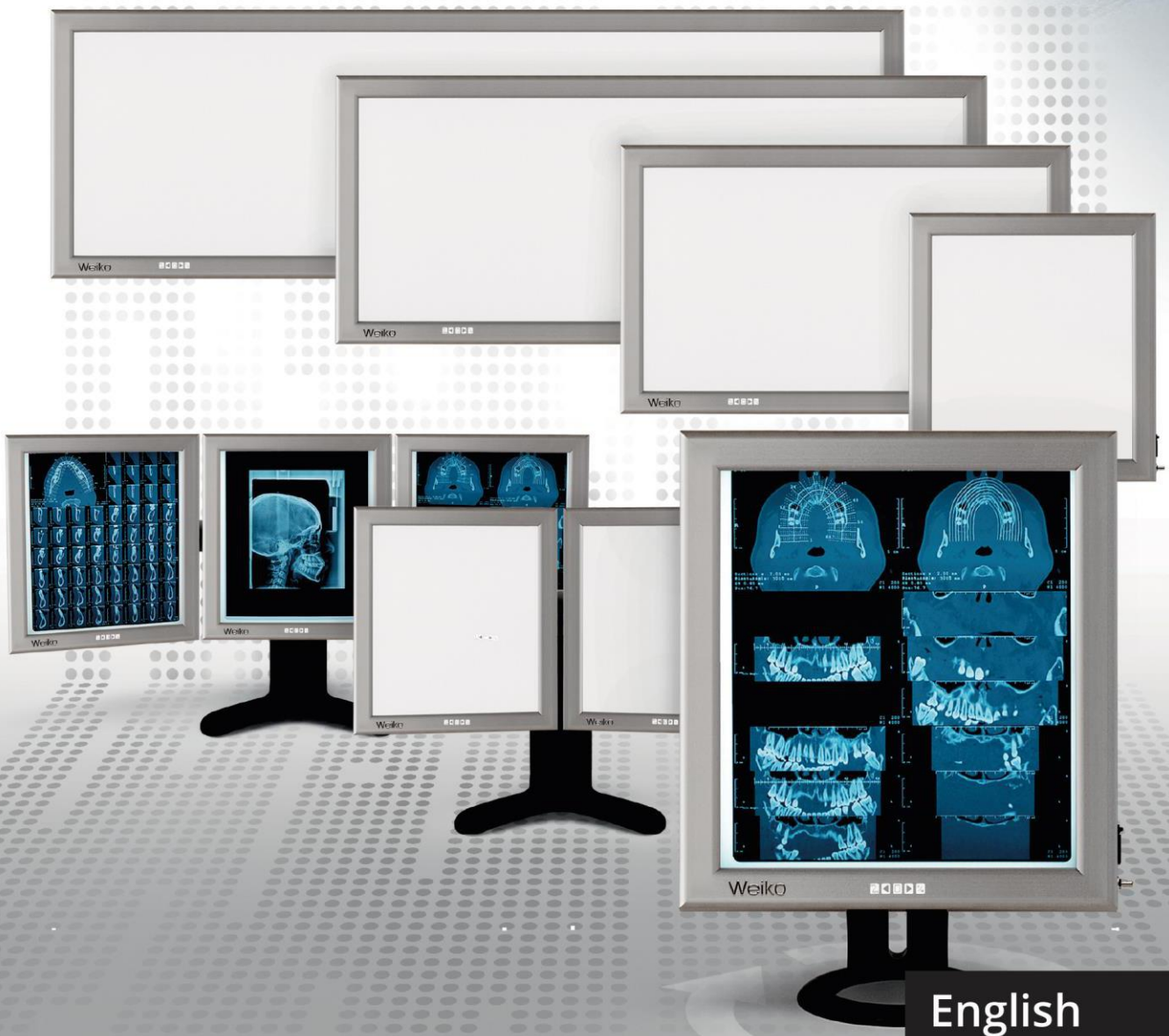


GIMA

ARTICOLI & APPARECCHI PER MEDICINA

SLIM LED VIEWERS

User Manual



English

Italiano

GIMA spa
Via Marconi 1 – 20060 Gessate (MI) – Italia
E-mail: gima@gimaitaly.com – www.gimaitaly.com
Tel.: 02 95 38 541 – Fax: 02 95 38 11 67.

ENG INDEX

1. Introduction
2. Important advice note
3. Product destination
4. Information
5. Technical data
6. Packaging handling
7. General warning
8. Special warning
9. Installation
10. Operating
11. Maintenance/Cleaning directions
12. Guarantee
13. EC Declaration of Conformity



Please read this manual with special care, before installing and operating the device.



ATTENTION: this symbol indicates the manual's sections that the user must fully understand and follow in order to avoid any potential damage to people and also to the equipment itself.

1. INTRODUCTION

Dear Customer,

your choice of our appliance means, for our Company, your particular recognition of the care of our designers, in the achievement of an ergonomic, reliable and pleasant design product.

We would thank you to trust our Company and we are at your complete disposal for everything you need.



2. IMPORTANT ADVICE NOTE

You are kindly requested to pay particular attention to this manual, before using the appliance, as it contains important recommendations on the correct installation, use and maintenance of the product.

As a matter of fact it is the shortest way of communication between the Supplier and the end User (p. 7.2.3 UNI EN ISO 13485:2012).

Have a good work!

3. PRODUCT DESTINATION

Our appliance, both in wall and table version (workstation), has been suitably designed to obtain the best backlight of the X-ray films to read and value them at one's best.

**This machine must only be used for the purpose for which it was designed.
All other uses must be considered dangerous.**

In this case the manufacturer can't be considered responsible for any damage caused by an incorrect use.

4. INFORMATION

Our SLIM LED viewers use the LEDs technology, the most advanced actually used in the lighting field.

The SLIM LED viewers are designed and assembled to work with separated or non separated panels, so that the panels can be set on either separately or all together.

Compared to the ones on sale, with high performance the SLIM LED viewer, has a special keyboard, placed on its down side, that allows the following operative systems:

- a. **TRADITIONAL:** manual switching on/off
- b. **FAS (Film Automatic Switching):** automatic switching on/off, at the positioning/removal of the X-ray film; **in the wall mounting version it is an optional while it is normally installed on Workstations.**
- c. **DIMMER:** luminance adjustment with range by 30% up to 100%. **It is normally installed on all versions.**

The use of LEDs technology allowing to obtain the following advantages:

1) OPERATIVE

- luminance increase
- uniform distribution of light with temperature of color more suitable to read the X-Ray films
- complete elimination of light flickering

2) ECONOMICAL

- viewer's average life increase (average life of LEDs 80.000/100.000 hours)
- reduction of electrical power consumption

3) ADDITIONAL ADVANTAGES

- depth of viewer only 3 cm
- vibrations and shock resistance, due to the use of "solid state" components
- eco-compatibility, as all the components are for limited environmental impact

The chassis is made of oven epoxy powder coated aluminum section, that doesn't let the structure become wasted.

The SLIM LED viewer is produced both in wall and table version (workstation).

5. TECHNICAL DATA

CODE	Wall version	Electrical supply	Power VA	External dimensions mm
BF LED 50.1	1 LED panel	110V-230V 50-60Hz	40	457 x 30 x 505
BF LED 50.2	2 LED panels	110V-230V 50-60Hz	80	817 x 30 x 505
BF LED 50.3	3 LED panels	110V-230V 50-60Hz	120	1177 x 30 x 505
BF LED 50.4	4 LED panels	110V-230V 50-60Hz	160	1537 x 30 x 505
BF LED 50.1 F	1 LED panel FAS	110V-230V 50-60Hz	40	457 x 30 x 505
BF LED 50.2 F	2 LED panels FAS	110V-230V 50-60Hz	80	817 x 30 x 505
BF LED 50.3 F	3 LED panels FAS	110V-230V 50-60Hz	120	1177 x 30 x 505
BF LED 50.4 F	4 LED panels FAS	110V-230V 50-60Hz	160	1537 x 30 x 505
CODE	Built-in version	Electrical supply	Power VA	External dimensions mm
BF LED 50.1 F I	1 LED panel FAS	110V-230V 50-60Hz	40	484 x 40 x 532
BF LED 50.2 F I	2 LED panels FAS	110V-230V 50-60Hz	80	844 x 40 x 532
BF LED 50.3 F I	3 LED panels FAS	110V-230V 50-60Hz	120	1204 x 40 x 532
BF LED 50.4 F I	4 LED panels FAS	110V-230V 50-60Hz	160	1564 x 40 x 532
CODE	Table version WORKSTATION	Electrical supply	Power VA	External dimensions mm
BF LED 50.1 F T1	1 LED panel	110V-230V 50-60Hz	40	457 x 30 x 505
BF LED 50.1 F T2	2 x 1 LED panels	110V-230V 50-60Hz	2 x 40	2 x (457 x 30 x 505)
BF LED 50.1 F T3	3 x 1 LED panels	110V-230V 50-60Hz	3 x 40	3 x (457 x 30 x 505)

F = FAS (Film Automatic Switching): in the wall mounting version it is an optional while it is normally installed on Workstations.

Specifications could be changed anytime.

6. PACKAGING HANDLING

After taking away the packaging, do not leave the different elements (carton boxes, plastic bags, polystyrene, etc.) in the environment and do not leave them in children hands, as they can be dangerous.

Anyway do not throw away the packaging before verifying the correct operation of the device, as in case of giving it back to the supplier, the device has to be put in its own original packaging.

All the different elements of the packaging, have to be handled following the local Directives regarding the disposal of the waste.

If it is necessary to dispose the SLIM LED viewer, at the end of its useful life, or for other reasons, it is important to consider that the SLIM LED viewer has to be disposed following the directions of the Directives that regulate the electromechanical/electrical devices, for which the same Directives require to reutilization/recycle the parts of the device, to avoid damages to the environment and consequently for the people health.

Ignoring the Directives regarding the disposal of the waste, please contact the qualified local Authorities.

7. GENERAL WARNING



After removing the packaging, check that the product has not been damaged in transit.

In case of doubt, do not attempt to repair or use the machine. Seek advice from a suitably qualified person. Packaging materials (plastic bags, polystyrene rubber, etc.) must be kept away from children, as they could cause harm.

This machine must only be used for the purpose for which it was designed.

All other uses must be considered dangerous.

The safe use of any electrical appliance involves the observance of certain basic rules, in particular:

- do not touch the appliance with damp hands;
- do not use the appliance while bare-foot;
- do not pull the plug from power socket by the power cord of the appliance itself;
- do not expose the appliance to adverse elements (sun, rain, etc.);
- do not let the children use the advice.

The manufacturer can't be considered responsible for damages caused by an incorrect use of the product.

8. SPECIAL WARNING



In case of any doubt on the safety of the advice, do not use it, and ask to a qualified person.

The electrical safety of this appliance is only guaranteed when it is correctly installed and connected to the grounded network, according to the latest issue of the Regulations Conformity with these requirements must be ensured and, in case of doubt, seek advice from a suitable qualified person.

Our Company can't be held responsible for any damage caused because the appliance has not been installed and earthed correctly.

Besides it is important to respect the following recommendations:

- check that the current carrying capacity of the wirings and socket are suitable for the maximum power of the device as shown on the label. In case of doubt, seek advice from a suitable qualified person
- to avoid dangerous overheating, it is advisable to fully unroll the power cord
- do not leave the appliance plugged in when unnecessarily.

If power cord becomes damaged, replace it promptly with the power cord:
EN 60 320-C15 - **outlet** CEI 23-16/VII (SCHUKO CEE 7-S.S. VII).

The manufacturer can't be considered responsible for any damage caused by an incorrect installation and earthing of the appliance.

9. INSTALLATION

The SLIM LED viewer has been tested in the factory, and its luminance has been adjusted at 100% of its maximum and it doesn't need any other adjustment or technical control after installation phase.

To install the SLIM LED viewer in wall version (Workstation) take care to the following directions:

1. the SLIM LED viewer has to be mounted on a steady and straight wall, through suitable bearings placed distant between themselves as the distance of the holes on the back of the advice;
2. do not install the SLIM LED viewer near the water as it could cause short circuit;
3. do not install the device near heat sources;
- 4.

To install the SLIM LED "BUILT-IN" version, please take care of the instructions put in the box.

To install the SLIM LED viewer in table version (Workstation) please take care to the special manual, where are described the assembling directions to place the viewer on the special support.

10. OPERATING

The SLIM LED viewer has a main switch O/I placed on the right side at the bottom and has also a little keyboard to start up the operating phase (see below figure).



The viewer has normally supplied with luminance adjusted at 100% maximum conditions.

To set on the appliance operate as follows:

1. connect the SLIM LED viewer to the plug trough the supplied power cord, paying attention that it is not damaged;
2. turn on the main switch from O position on the right side to I position; in this mode starts to flash the light (A) in the middle of the keyboard and is possible to operate in different modes:

TRADITIONAL

In the condition reported in the aforesaid point 2., with light (A) flashing, press the ON/OFF key (D).

When the light (A) stops flashing but keeps lighted, press the A/M key (E).

The viewer lights on with normal luminance at the 100%.

Then go to operate according point 3.

FAS (Film Automatic Switching)

In the condition reported in the aforesaid point 2., with light (A) flashing, press the ON/OFF key (D).

The light (A) stops flashing but keeps lighted.

The viewer is ready to work in FAS mode with automatic switching on/off, at the positioning/removal of the X-ray film.

Then go to operate according point 3

DIMMER

The luminance, either in TRADITIONAL mode or in FAS mode, can be tuned in a range between 30% and 100% of its maximum value, press the left key (B) to decrease the value of luminance or press the right key (C) to increase it.

3. insert the X-ray film under the frame of the SLIM viewer.

To install the SLIM LED viewer in table version (workstation) – after assembling it on the suitable equipped support (see specific manual) – put it on the desk in the preferred position following the above points 1, 2 and 3.

The viewer in table version has the chance to be adjusted in its space positioning (up/down, side to side rotation, forward/backward rotation) (see the special manual) to allow the operator to work in the most comfortable conditions.

11. MAINTENANCE / CLEANING DIRECTIONS



The SLIM LED viewer doesn't need any advanced maintenance, but, if it is out of order, verify and eventually change the fuse if damaged (1 panel 1A, 2 panels 1A, 3 panels 2A, 4 panels 2A).

If the appliance persists in being out of order, ask to your supplier.

The SLIM LED viewer needs only the routine cleaning which is easily done because every part is easy to reach.

Before any phase of maintenance, do not leave the appliance plugged.

Do not use any solvent to clean the appliance.

12. GUARANTEE

The manufacturer guarantees the good quality of the parts of the device, assuring, during the warranty period, to repair or replace as soon as possible, defected parts, if it depends on the manufacturer itself or on the Force Majeure.

We always guarantee our devices for 24 months, from the date of the purchase.

Parts acquired from other manufacturers have the same guarantee that is given us by the manufacturer.

Parts subject to normal wear as plastic parts, glass, neon, starter, etc., are excluded from the gurantee.

Shipping costs are paid by the Customer.

All risks during the transport are under responsibility of the Customer.

The repairing actions do not modify the expiry date of guarantee.

The Customer must send the device to manufacturer, with a photocopy of the purchase invoice, where is signed the date of the purchase and the appliance number.

Further claims from the purchaser for reimbursement of damages not attributable to the manufacturer, are obviously not taken in consideration.