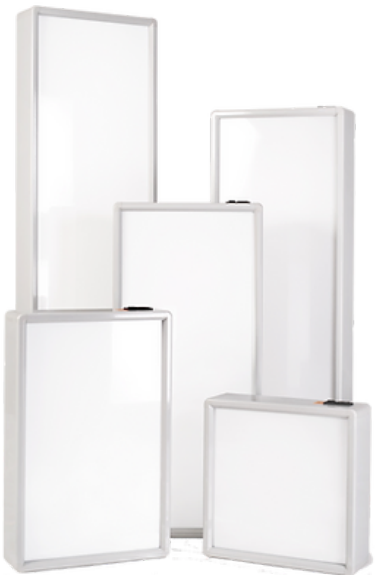
X-Ray Film Viewers STANDARD



- **Chassis** composed of oven-fired epoxy powder coated aluminum (RAL7035)
- **Light Source** with straight daylight fluorescent tubes, by 15W up to 58W
- **Diffusing** Panel with acrylic sheet of 3 mm thickness
- Built-in film grip
- **Power Supply**: 230V; 50/60 Hz
- **Switch**: ON/OFF bipolar switch with two pole fused plug
- **Cable**: made of pre-insulated terminals in self extinguishing PVC
- **All components UL** - DVE- IMQ approved
- The device complies with the essential requirements of the Low Voltage Directive 2006/95/CE and with the essential requirements of the Electro Magnegtic Compatibility 2004/108/CE. It complies with Directive 2007/47/CE as a Medical Device Class 1.

Types	Code	N° switches	Viewing area (cm)	External dimensions (cm)			Net weight Kg	Temperature of colour	Luminous flux (lm)	Chromatic index	Total Power (Watt)
				Width	Height	Depth					
1 Panel	BF AL 43.43 OR	1	38x38	43	43	12	6	6500	2x700	63	2x15
1 Panel	BF AL 43.43D	1	38x38	43	43	12	6	6500	2x700	63	2x15
1,5 Panels	BF AL 43.70 OR	1	38x62	67	43	12	8	6500	2x1100	63	2x18
2 Panels	BF AL 43.90 OR	1	38x92	97	43	12	11	6500	2x1700	63	2x30
3 Panels	BF AL 43.120 OR	1	38x122	127	43	12	14	6500	2x2850	63	2x36
4 Panels	BF AL 43.150 OR	1	38x153	158	43	12	18	6500	2x4600	63	2x58

Digitally signed by Potînga Stela
Date: 2022.07.20 14:12:03 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

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

CERTIFICATE

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.

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

SGQ N° 007A

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

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:

BFAL 43.43 OR - BFAL 43.70 OR - BFAL 43.70 OV
BFAL 43.70 VE - BFAL 43.90 OR - BFAL 43.90 OV
BFAL 43.90 VE - BFAL 43.120 OR - BFAL 43.120 OV
BFAL 43.120 VE - BFAL 43.150 OR - BFAL 43.150 OV
BFAL 43.150 VE - BFAL 86.120 OR - BFAL 86.150 OR

leading to the product family:

STANDARD VIEWER

BASIC UDI-DI: 805373671BFAL_NEGWY

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

Rev.02 – 13 May 2021