

**EU DECLARATION OF CONFORMITY**  
**MDR 2017/745**

**TITANOX S.r.l.**

**Via Canove de' Biazzi - 26038 TORRE DE' PICENARDI (CR) - Tel: 0375394065**

**E-mail: [info@titanox.it](mailto:info@titanox.it) - SRN: IT-MF-000020325**

**Hereby declare under their own responsibility that**

**MEDICAL DEVICES CALLED**  
**" X-RAY FILM VIEWER",**

**BASIC UDI-DI: 805930470M05H4**

**MANUFACTURED BY TITANOX S.R.L.,**

**ARE COMPLIANT WITH THE ESSENTIAL SAFETY AND PERFORMANCE**  
**REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL DEVICES**  
**REGULATION 2017/745.**

such medical device is complying with all the applicable requirements of the Medical Devices Regulation 2017/745, in particular:

- That the medical device above belongs to Class I, according to Annex VIII of the Medical Devices Regulation 2017/745, rule 1;
- That the medical device above HAS NO MEASURING FUNCTION;
- That the medical device above IS NOT TO BE USED FOR CLINICAL INVESTIGATION;
- That the medical device above IS NOT MARKETING IN A STERILIZED PACKAGE;

*We certify that the devices also comply:*

**DIR. 2014/30/UE – Electromagnetic compatibility (EMC)**


**DIR. 2014/35/UE – Low voltage (LVD)**

**DIR. 2011/65/UE – Directive ROHS II**

**DIR. 2015/863/UE – Modified Ann. II Directive ROHS II**

*Torre de' Picenardi 12.05.2022*

.....  
(place and date of issue)

  
Sole Administrator  
Enrico Basatti

.....  
(name and signature or stamping of the authorized person)

Annex list of devices covered by this declaration

Code	Description
M604043	X-RAY FILM VIEWER 40X43
M604043/M	X-RAY FILM VIEWER 40X43 1 PANEL WITH LIGHT DIMMER
M608043	X-RAY FILM VIEWER 80X43
M608043/GM	X-RAY FILM VIEWER 80X43 2 PANELS WITH LIGHT DIMMER
M612043	X-RAY FILM VIEWER 120X43
M612043/GM	X-RAY FILM VIEWER 120X43 3 PANELS WITH LIGHT DIMMER
M612043/V	X-RAY FILM VIEWER 120X43 VERTICAL
M616043	X-RAY FILM VIEWER 160X43