EU DECLARATION OF CONFORMITY
MDR 2017/745

TITANOX S.r.l.

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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 MARKETED 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 Busatti
(name and signature or stamping of the authorized person)

Rev. 01 dated 12.05.2022

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2024.07.17 13:40:29 EEST
Reason: MoldSign Signature
Location: Moldova

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