

CE DECLARATION OF CONFORMITY

TITANOX S.r.l.
Via Canove de' Biazzi 2/A
26038 TORRE DE' PICENARDI (CR)

CE DECLARATION OF CONFORMITY OF THE MEDICAL DEVICE "X-RAY FILM VIEWER",
MANUFACTURED BY TITANOX S.r.l., WITH THE ESSENTIAL REQUIREMENTS SET FORTH IN ANNEX I OF THE
MEDICAL DEVICES DIRECTIVE 93/42/EEC.

M604043 M604043/M M608043 M608043/G M608043/GM
M612043 M612043/V M612043/VM M612043/G M612043/GM M616043 M616043/G

The undersigned TITANOX S.r.l., with residence in Torre de' Picenardi, manufacturer of the medical device mentioned above hereby declare under their own responsibility that such medical device is complying with all the applicable requirements of the Medical Devices Directive 93/42/EEC.

The undersigned declare that:

- the medical device above complies with the Essential Requirements list in Annex I of the Medical Devices Directive 93/42/EEC;
- the medical device above belongs to Class I;
- the medical device above HAVE NO MEASURING FUNCTION;
- the medical device above IS NOT TO BE USED FOR CLINICAL INVESTIGATION;

The undersigned declare that a systematic procedure has been instigate and kept up to date to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product..

The undersigned shall make the documentation required by Annex VII of the Medical Devices Directive 93/42/EEC, including the declaration of conformity; available to the National Authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.

declare under our responsibility that the product to which this declaration relates is in conformity with the following standards or other normative document(s):

DIRECTIVE 2004/108/CE – Electromagnetic Compatibility (EMC)

DIRECTIVE 2006/95/CE - Low Voltage

Torre de' Picenardi 2013-03-21
(luogo e data di emissione)


Enrico Busatti
(nome e firma o timbratura equivalente della persona autorizzata)

List of medical devices of the present declaration.

TITANOX S.r.l.	CE DECLARATION OF CONFORMITY 93/42/CEE	
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Codes	Description
M604043	X-RAY FILM VIEWER 40X43
M604043/M	X-RAY FILM VIEWER 40X43 ONE PANEL WITH LIGHT DIMMER
M608043	X-RAY FILM VIEWER 80X43
M608043/G	X-RAY FILM VIEWER 80X43
M608043/GM	X-RAY FILM VIEWER 80X43 TWO PANELS WITH LIGHT DIMMER
M612043	X-RAY FILM VIEWER 120X43
M612043/G	X-RAY FILM VIEWER 120X43
M612043/GM	X-RAY FILM VIEWER 120X43 THREE PANELS WITH LIGHT DIMMER
M616043	X-RAY FILM VIEWER 160X43
M616043/G	X-RAY FILM VIEWER 160X43
M612043/V	X-RAY FILM VIEWER 120X43 VERTICAL
M612043/VM	X-RAY FILM VIEWER 120X43 VERTICAL WITH LIGHT DIMMER