EC Certificate
Full Quality Assurance System

Digitally signed by Trocin Caterina
Date: 2020.11.18 11:30:33 EET
Reason: MoldSign Signature
Location: Moldova

Certificate No.:	Project No.:	Valid until:
216568-2017-CE-ITA-NA-PS Rev 0.0	PRJC-57542-2008-MSL-ITA	12.04.2022

This is to certify that the quality system of:

ITALRAY S.r.l.
Via del Parlamento Europeo, 9/D
50018 Scandicci (FI)
Italy

For design, production and final product inspection/testing of:

Radiological Equipment

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 april 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus
Certification Manager

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the Certificate 141313-2013-CE-ITA-NA (NB 0434) and merge the Certificate 91212-2011-CE-ITA-NA (NB 0434) following the transfer of Notified Body function to DNV GL NEMKO Presafe AS (NB 2460). Issued after recertification.	2017-04-12

Products covered by this Certificate:

Product Description	Product Name	Class
X-ray Generator	PIXEL HF: - GX-100K e VOXEL HF, PIXEL HF TS: - GX-200K TS , VOXEL HF TS PIXEL CP Series PIXEL DRF Series	IIb
X-ray Image Recording and processing System	- X-FRAME CCD - DIGIVIEW A - AQUIRE - X-FRAME CCD@ - DIGIVIEW B - AQUIRE 40 - X-FRAME DR - DIGIVIEW DR - AQUIRE DR - X-FRAME DRF@	IIb
Analogue general-purpose mobile diagnostic X-ray System	- CORSIX - CORSIX – R	IIb
X-ray Image Recording and processor	- X-FRAME DR EZ - DIGIVIEW DR EZ - AQUIRE DR EZ	IIb

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Product Description	Product Name	Class
Portable general-purpose diagnostic	- CARMEX - CARMEX-R - CARMEX RK 15 - CARMEX I Series	IIb
General purpose x-ray examination table	- CLINODIGIT EVO - CLINODIGIT EVO @	IIb
Digital general-purpose mobile diagnostic X-ray system	- XFM - CORSIX DR - X-FRAME DR MOBILE	IIb
General purpose x-ray examination table	CLINODIGIT OMEGA	IIb
Radiographic/Fluoroscopic Table System	CLINODIGIT OMEGA SYSTEM	IIb
Digital stationary X-ray diagnostic system	- X-FRAME DR2T SYSTEM - X-FRAME DRT SYSYEM - X-FRAME DR2S SYSTEM	IIb
Mammograph	- MAMMOGRAPH - MAMMOGRAPH FFDM - MAMMOGRAPH D-TOMO	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

ITALRAY S.r.l., Via del Parlamento Europeo, 9/D, 50018 Scandicci (FI) Italy

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate