



DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 54272-2009-CE-KOR-NA 2.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Eco Ray Co., Ltd.

Korea

for design, production and final product inspection/testing of

X-Ray System

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 are given overleaf

Place and date:

Høvik, 04 March 2011

This Certificate is valid until:

04 June 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



Eugenie Winger Husebye

Eugenie Winger Husebye
Certification Manager

Notified Body No.:
0434

Mariann Jeremiassen
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.





Cert. No.: 54272-2009-CE-KOR-NA
Rev. No.: 2.0
Project No.: PRJC-143203-2009-PRC-KOR

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
	Original certificate	2009-06-04
1	Extension in scope – new models added (in bold)	2009-10-02
2	Address changed (Manufacturer & EUR)	2011-03-04

Products covered by this Certificate

Product Description	Product Name	Class
Portable X-Ray Units	- ANYPLX 4, ORANGE 10025HF, ORANGE 1025HF, ORANGE 1025 - ULTRA 10025HF, ULTRA 1025HF, ULTRA LIGHT	IIb
Portable X-Ray Units	- ANYPLX 5, ORANGE 10040HF, ORANGE 1040HF, ORANGE 1040 - ULTRA 10040HF, ULTRA 1040HF, ULTRA 100HF, ULTRA PLUS	IIb
Portable X-Ray Units	- ANYPLX 7, ORANGE 10060HF, ORANGE 1060HF, ORANGE 1060 - ULTRA 10060HF, ULTRA 1060HF, ULTRA 100 PLUS	IIb
Portable X-Ray Units	- ANYPLX 3, ORANGE 8016HF, ORANGE 8016 - ULTRA LIGHT 8016HF, ULTRA 8016, ULTRA LIGHT MINI - MINI 80	IIb
Portable X-Ray Units	- ANYPLX 3 PLUS, ORANGE 9020HF, ORANGE 9020 - ULTRA LIGHT 9020HF, ULTRA 9020 - MINI 90	IIb
Digital Radiography System	- FXD-900	IIb

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
EcoRay Co., Ltd.	#402, 4F., Cygnus B/D, 115-12, Nonhyun-Dong, Kangnam-Ku, Seoul, 135-821, Korea

EU Representative

Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway. Tel: +47 67 57 9900 Fax: +47 6757 9911 www.dnv.com
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BCF Technology,
3 Tailend Court, Starlaw Road, Livingston, West Lothian, Scotland, UK EH54 8TE

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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE

