

ECORAY

EcoRay Co., Ltd.

#402, 4F Cygnus B/D, 115-12, Nonhyun-dong, Kangnam-gu, Seoul, KOREA 135-821

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EC DECLARATION OF CONFORMITY

Manufacturer: EcoRay Co., Ltd.

Address: #402, 4F, Cygnus B/D, 115-12, Nonhyun-Dong, Kangnam-Ku, Seoul, KOREA, 135-821

European representative: BCF Technology Co., Ltd.

Address: 3 Tailend Court Starlaw Raod Livingston Scotland UK EH54 8TE

Notified Body: DET NORSKE VERITAS (DNV)

Address: Veritasveien 1, 1322 HOVIK, Norway

Product: Portable X-Ray Unit

Model: ANYPLX 5

(ORANGE 10040HF, ORANGE 1040HF, ORANGE 1040, ULTRA 10040HF, ULTRA 1040HF, ULTRA 100HF, ULTRA PLUS)

Classification: Class II b by Rule 10 of Annex IX, MDD 93/42/EEC as amended by 2007/27/EC

Conformity Assessment Route: Annex II, Exclusive Section 4, MDD 93/42/EEC as amended by 2007/47/EC

We hereby declare that the complies with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the devices are intended to be placed on the market) using Annex II, Exclusive Section 4, as the conformity assessment procedure via DNV (NB 0434) as the Notified Body.

- EN 60601-1-2:2001 (EMC)
- EN 55011:2007/A2:2007 (EMC)
- EN 60601-1:1990/A1:1991, A2:1995 (SAFETY)
- EN 60601-1-3: 1995 (SAFETY)
- EN 60601-2-7: 1998 (SAFETY)
- EN 60601-2-28: 1993 (SAFETY)

Person responsible for making this declaration Place, Seoul, Korea

Date of Issue: JUNE, 2011

Signature:
Name/Title:

DONG-WOOG LEE/PRESIDENT
DON LEE / President