EC Declaration of Conformity

This document declare that the following designated product

VATECH Co., Ltd.

23-4, Seogu-dong, Hwaseong-si, Gyeonggi-do, 445-170, Korea

Product Name : Digital X-ray Imaging System
Model Name : PCH-2500

Has been classified as Class IIb (according to Annex 9, Rule 10) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC, is subject to the procedures set out in Annex II of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body SGS (code no. : 0120) of British.

Related standards for Medical devices directive 93/42/EEC as amended by 2007/47/EC as demonstrated by compliance with;
Safety : EN60601-1:90+A1:93+A2:95, EN 60601-1-3:94, EN 60601-2-7:98, EN 60601-2-28:93, EN 60601-2-32:94
EMC : EN60601-1-2:01+A1:06

The above product herewith complies with the requirements of Medical device directive 93/42/EEC as amended by 2007/47/EC and relevant harmonized standards applied for the above product, and a declaration of conformity with the medical device directive has been completed and signed by the manufacturer.

Republic of Korea / 21 December 2011

Authorized representative established within the EU
Company Name : Vatech Dental Manufacturing Ltd.
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Digitally signed by Sajin Alexandru
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Reason: MoldSign Signature
Location: Moldova

Sung-Hee Park
Chief of Regulatory Affair
For and on behalf of VATECH Co., Ltd.