

EC Declaration of Conformity

This document declare that the following designated product



13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449 KOREA

Product Name: Digital X-ray Imaging System

Model Name: PCH-30CS

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 excl. section IV of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body DNV GL Business Assurance Norway AS (code no.: 0434) of Norway.

The above product herewith complies with the requirements of the Medical device directive 93/42/EEC as amended by 2007/47/EC as transposed into national legislation of the member states where the product is placed on the market 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. We are exclusively responsible for the declaration of conformity.

Republic of Korea / July 19, 2017

Notified Body: DNV GL Business Assurance Norway AS

- Address: Veritasveien 1, 1322 HOVIK, Norway

Authorized representative established within the EU

- Company Name: Vatech Dental Manufacturing Ltd.
- Company Address: Suite 3, Ground Floor, Chancery House, St. Nicholas Way, Sutton, SM1 1JB UK

Won Bin, Kim
Quality Management Representative
VATECH Co., Ltd.

A handwritten signature in black ink, appearing to read "Won Bin, Kim", is written over a horizontal line. The signature is stylized and somewhat abstract.