

EC Declaration of Conformity

This document declare that the following designated product



13, Samsung 1-ro 2-gil, Hwaseoung-si, Gyeonggi-do, Korea

Product Name : Computed Tomography X-ray System

Model Name : PHT-30LFO

Has been classified as Class IIb (according to Annex 9, Rule 5, Rule 10, Rule 16) 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 Presafey Denmark A/S (code no. : 0543 / ID of certificate: DGM-819) of Denmark.

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.

Republic of Korea / 12 November 2014

Notified Body : Presafe Denmark A/S (Address: Tuborg Parkvej 8, DK-2900 Hellerup, Denmark)

Authorized representative established within the EU

Company Name : Vatech Dental Manufacturing Ltd.

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