

EC Declaration of Conformity

This document declare that the following designated product

Product Name: Computed Tomography X-ray System

Model Name: PHT-75CHS

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 Nemko Presafe AS (code no. : 2460).

The above product herewith complies with the requirements of the Restriction of the use of certain Hazardous Substances(RoHS) Directive 2011/65/EU and 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 / 12 March 2020

Notified Body: DNV GL Nemko Presafe AS

- Address: Veritasveien 3, N-1363 HOVIK, Norway

Authorized representative established within the EU

- Company Name: Vatech Global France (SARL).
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