

Declaration of Conformity

This document declares that the following designated product

Product Name: Digital X-ray Imaging System

Model Name: VistaPano S Ceph

Brand Name: VistaPano S Ceph 2.0

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 Product Assurance AS (code no.: 2460, Certificate no.: 10877-2017-CE-KOR-NA-PS Rev 3.0).

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 / 29 January 2024

Notified Body: DNV Product Assurance AS

- Address: Veritasveien 1, 1363 Høvik, Norway

Authorized representative established within the EU

- Company Name: VATECH GLOBAL FRANCE SARL

- Company Address: 49 Quai de Dion Bouton, AVISO A 4ème étage, 92800 Puteaux, France

Shin Ki Sang
Quality Management
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