VATECH Co., Ltd.
13, Samsung 1-ro 2-gil,
Hwaseong-si, Gyeonggi-do,
18449, Korea

Declaration of Conformity

This document declare that the following designated product

Product Name: Dental X-ray System with Extraoral Source X-ray System
Model Name: VistaIntra DC (2202-03)

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).

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 / 20th October 2023
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 Representative
VATECH Co., Ltd.

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