

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 : Dental X-ray System

Model Name : VEX-S300W

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 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 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 / 14 November 2016

Notified Body: DNV GL Business Assurance Norway AS

- Address: Veritasveien 1, 1322 HOVIK, Norway

Authorized representative established within the EU

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