

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10877-2017-CE-KOR-NA-PS Rev. 3.0

Project No.:
PRJC-527965-2015-MSL-KOR

Valid Until
26 May 2024

This is to certify that the quality system of:

VATECH Co., Ltd.

13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449 KOREA

For design, production and final product inspection/testing of:

**Computed Tomography X-ray System,
Digital X-ray Imaging system,
Dental X-ray System with Extraoral Source X-Ray System**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 May 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Hazem Tinawi
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 8022-2016-CE-KOR-NA (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	03 October 2017
1.0	EU Rep Change	12 March 2020
2.0	MDD Re-certification	23 April 2021
3.0	Alternate model names added	06 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Computed Tomography X-ray System (GMDN: 44245)	<ul style="list-style-type: none"> PHT-6500 PHT-60CFO PHT-30LFO PCH-90LH PHT-35LHS PHT-65LHS PHT-30CSS PHT-75CHS 	IIb
Digital X-ray Imaging system (GMDN: 44245)	<ul style="list-style-type: none"> PCH-2500 PCH-30CS VistaPano, ProVecta S-Pan VistaPano S VistaPano S Ceph, ProVecta S-Pan Ceph 	IIb
Dental X-ray System with Extraoral Source X-Ray System (GMDN: 44606)	<ul style="list-style-type: none"> VEX-S100W VistaIntra DC, ProVecta HD VEX-P300 VEX-S300W 	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
VATECH Co., Ltd.	13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449 KOREA

EU Representative

Vatech Global France (SARL)
51 Quai de Dion Bouton 92800 Puteaux France

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate