DNV

EC CERTIFICATE
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
10877-2017-CE-KOR-NA-PS Rev. 3.0	PRJC-527965-2015-MSL-KOR	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

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)	• PHT-6500 • PHT-60CFO • PHT-30LFO • PCH-90LH • PHT-35LHS • PHT-65LHS • PHT-30CSS • PHT-75CHS	IIb
Digital X-ray Imaging system (GMDN: 44245)	• 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)	• VEX-S100W • VistaIntra DC, **ProVecta HD** • VEX-P300 • VEX-S300W	IIb

The complete list of devices is filed with the Notified Body

Certificate No.: 10877-2017-CE-KOR-NA-PS Rev. 3.0
Place and date: Høvik, 06 May 2021

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

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10877-2017-CE-KOR-NA-PS Rev 3.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:

VATECH Co., Ltd.

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

originally issued in compliance with:

the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Place and date:
Høvik, 10 August 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Mariann Jeremiassen
Principal Assessor

The name or identifier of a device already covered by the certification, has been revised.

Products covered by this Certificate (replaces information on certificate):		
Product Description	**Product Name**	**Class**
Computed Tomography X-ray System (GMDN: 44245)	• PHT-6500 • PHT-60CFO • PHT-30LFO • **PCT-90LH** • PHT-35LHS • PHT-65LHS • PHT-30CSS • PHT-75CHS	IIb
Digital X-ray Imaging system (GMDN: 44245)	• 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)	• VEX-S100W • VistaIntra DC, ProVecta HD • VEX-P300 • VEX-S300W	IIb

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	The name or identifier of a device already covered by the certification, has been revised. (PCH-90LH -> PCT-90LH)	10 August 2021

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10877-2017-CE-KOR-NA-PS Rev 3.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
VATECH Co., Ltd.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A new EU representative address, replacing the one stated on the certificate, has been accepted.

EU Representative
VATECH GLOBAL FRANCE SARL 49 Quai de Dion Bouton, AVISO A 4ème étage, 92800 Puteaux, France

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	The name or identifier of a device already covered by the certification, has been revised (PCH-90LH -> PCT-90LH)	10 August 2021
1.0	A new EU representative, replacing the one stated on the certificate, has been accepted. (Address of EU representative is changed)	03 February 2023

Place and date:
Høvik, 03 February 2023

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer