

## **Quality System Certificate**

Certificate Number:

DGM - 820

This is to certify that the quality system of:

Vatech Co., Ltd.

13, Samsung 1-ro 2-gil Hwaseong-si Gyeonggi-do 445-170 Korea

fulfills the requirements in:

ISO 13485:2003 and EN ISO 13485:2012

The certificate covers the following activities:

Design, Manufacture, Distribution, Installation and Servicing of Computed Tomography X-Ray System, Digital Imaging System, Dental X-Ray Systems with Extraoral Source X-Ray System

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Authorized person

For Presale Denmark A/S

Date of issue:

2014-11-12

Expires:

2020-01-20

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Reference:

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Presafe Denmark A/S

Tuborg Parkvej 8 2900 Hellerup Denmark

