

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
9787-2017-CE-KOR-NA-PS Rev. 4.0

Project No.:  
PRJC-514731-2014-MSL-KOR

Valid Until:  
26 May 2024

This is to certify that the quality system of:

### DK Medical Systems Co., Ltd.

52, Chupalsandan 1-gil, Paengseong-eup, Pyeongtaek-si, Gyeonggi-do, Korea

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

**Radiographic X-ray system, Mobile C-Arm X-ray system,  
Digital Radiographic X-ray system,  
Portable 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, 26 February 2020



For:  
DNV GL PRESAFE AS

Notified Body No.: 2460

*Eugenie Winger Husebye*  
Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



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**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
	Replaces certificate 5849-2015-CE-KOR-NA 2.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-17
1.0	Scope extension_new model added (in bold)	2017-10-27
2.0	Re-certification	2020-01-07
3.0	Editorial change	2020-01-20
<b>4.0</b>	<b>Products cancellation(DKII-325R, DKII-525R)</b>	2020-02-26

Products covered by this Certificate:

Product Description	Product Name	Class
<b>Radiographic X-ray system</b>	<ul style="list-style-type: none"> <li>AccuRay 630R, AccuRay 525R</li> </ul>	IIb
<b>Digital Imaging System</b>	<ul style="list-style-type: none"> <li>ELTOR</li> </ul>	IIb
<b>Mobile C-Arm X-ray system</b>	<ul style="list-style-type: none"> <li>PROSTAR</li> </ul>	IIb
<b>Digital Radiographic X-ray system</b>	<ul style="list-style-type: none"> <li>INNOVISION-EXII, INNOVISION-DXII</li> </ul>	IIb
<b>Portable X-ray system</b>	<ul style="list-style-type: none"> <li>Elpo-32</li> </ul>	IIb

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
DK Medical Systems Co., Ltd.	52, Chupalsandan 1-gil, Paengseong-eup, Pyeongtaek-si, Gyeonggi-do, Korea

**EU Representative**

Obelis S.A, Bd. Général Wahis 53 1030 Brussels, BELGIUM

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## 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate