DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
248064-2017-CE-KOR-NA-PS Rev. 5.0	PRJC-551628-2016-MSL-KOR	28 May 2023

This is to certify that the quality system of:

FINEMEDIX CO., LTD.

60, Maeyeo-ro, Dong-gu, Daegu, 41065, Korea

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

Endoscopic electric devices and Endoscopic non-electric devices

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, 30 January 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Palani Damodharan

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

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Valid Until:
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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
0.0	Original Certificate	28 May 2018
1.0	Scope Extension_model added	04 December 2018
2.0	Product Name changed	18 February 2019
3.0	Scope Extension_model added	02 December 2019
4.0	Editorial change	17 December 2019
5.0	**Scope Extension_model added (in Bold)**	**30 January 2020**

Products covered by this Certificate:

Product Description	Product Name	Class
Endoscopic electric devices	ClearCut Knife	IIb
	ClearGrasp Snare	
	ClearCoajet	
	FineTome	
	ClearHemograsper	
	Clear-Hemostat	
	Clear-CoaBite	
Endoscopic non-electric devices	Clear-Jet Injection Catheter	IIa
	Clear-Bite Biopsy Forceps	IIa
	Clear-Retriever	IIa
	ClearTip	IIa
	ClearCap Distal Attachment	Is
	ClearEndoclip	**IIa**
	Fine-Grab Basket	**IIa**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
FINEMEDIX CO., LTD.	60, Maeyeo-ro, Dong-gu, Daegu, 41065, Korea

EU Representative
Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany

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