



EC Certificate Full Quality Assurance System

Certificate No.:
253866-2018-CE-IND-NA-PS Rev. 4.0

Project No.:
PRJC-565765-2017-MSL-IND

Valid Until:
08 June 2023

This is to certify that the quality system of:

SHAILI ENDOSCOPY

PLOT NO. 210 & 213, PADRA JAMBUSAR ROAD,
VILLAGE: DABHASA, TAL: PADARA,
Dist: VADODARA – 391440, GUJARAT, INDIA

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

Devices for Gastroenterology, Urology

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, 22 March 2019



For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.no/digital_signatures for more info.

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



Management System Certificate

Certificate No.:

Initial Certification Date:

Valid Until

251747-2017-AQ-IND-NA-PS Rev. 2.0

8 March 2018

7 March 2024

This is to certify that the quality system of:

SHAILI ENDOSCOPY

PLOT NO. 210 & 213, PADRA JAMBUSAR ROAD, VILLAGE: DABHASA, TAL: PADRA,
VADODARA – 391440, GUJARAT, INDIA

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

**Design, Manufacture and supply of Urology, Bronchoscopy, Gastroenterology and
Gynecology Medical Devices**

Place and date:
Høvik, 4 March 2021

For the issuing office:
DNV Product Assurance AS

Check Validity



Eugenie Winger Husebye
Eugenie Winger Husebye
Technical Reviewer

MSYS 018

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

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

ICP-4-5-11-ISO13485-11,

rev.0

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000463105-PA-NoMA-IND Rev. 1

Project No.:
PRJC-565765-2017-MSL-IND

Valid Until
27 May 2024

This is to certify that the quality system of:

SHAILI ENDOSCOPY

PLOT NO. 210 & 213, PADRA JAMBUSAR ROAD, VILLAGE: DABHASA, TAL: PADRA, Dist: VADODARA –
391440, GUJARAT, INDIA

For design, production and final product inspection/testing of:
DEVICES FOR GASTROENTEROLOGY, UROLOGY

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, 24 May 2021

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




Palani Damodharan
Principal Assessor

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



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VILLAGE: DABHASA, TAL: PADARA,
Dist: VADODARA – 391440, GUJARAT, INDIA

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

Devices for Gastroenterology, Urology

Has been assessed with respect to:

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