



Certificate

No. Q8 022801 0008 Rev. 00

Holder of Certificate: **PENTAX Europe GmbH**
Julius-Vosseler-Str. 104
22527 Hamburg
GERMANY

Certification Mark:



Scope of Certificate: **Purchase, storage, packaging, sales and service of medical endoscopes, light sources, video processors, therapeutic platforms and instruments and accessories, contract manufacturing of endoscopes**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8 022801 0008 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q8_022801_0008_Rev._00)

Report No.: 713204360

Valid from: 2021-08-04

Valid until: 2024-08-01

Date, 2021-08-04



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q8 022801 0008 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

PENTAX Europe GmbH

Julius-Vosseler-Str. 104, 22527 Hamburg, GERMANY

Purchase, storage, packaging, sales and service of medical endoscopes, light sources, video processors, therapeutic platforms and instruments and accessories

PENTAX Europe GmbH Service-Center Potsdam

Großbeerenstraße 187, 14482 Potsdam, GERMANY

Service of medical endoscopes, light sources, video processors and accessories

PENTAX Medical Bulgaria EOOD

Vasil Levski str. 179, 4003 Plovdiv, BULGARIA

Purchase, storage, packaging and service of medical endoscopes, light sources, video processors and accessories, contract manufacturing of endoscopes

PENTAX U.K. Limited

Heron Drive, Langley, Slough SL3 8PN, UNITED KINGDOM

Purchase, storage, packaging, sales and service of medical endoscopes, light sources, video processors, therapeutic platforms and instruments and accessories

PENTAX Nederland B.V.

Edisonring 4, 6669 NB Dodewaard, THE NETHERLANDS

Purchase, storage, packaging, sales and service of medical endoscopes, light sources, video processors, therapeutic platforms and instruments and accessories

PENTAX Nederland B.V. Sales Branch Office Belgium

Lieven Geværtstraat 15, 2950 Kapellen, BELGIUM

Sales of medical endoscopes, light sources, video processors, therapeutic platforms and instruments and accessories



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
242366-2017-AQ-TWN-NA-PS

Initial certification date:
06 September 2017

Valid:
28 February 2022 – 27 February 2025

This is to certify that the management system of

ONYX Healthcare Inc.

2F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien Dist., New Taipei City 231, Taiwan

and the sites as mentioned in the appendix accompanying this certificate

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

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Assembly, Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.

Place and date:
Høvik, 09 February 2022



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway - TEL: +47 67 57 99 00. www.dnv.com



Certificate no.: 242366-2017-AQ-TWN-NA-PS
Place and date: Høvik, 09 February 2022

Appendix to Certificate

ONYX Healthcare Inc.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
ONYX Healthcare Inc.	2F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien Dist., New Taipei City 231, Taiwan	Design, Assembly, Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.
ONYX Healthcare USA, Inc.	324 West Blueridge Avenue, Orange, CA, 92865, USA	Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.

