



Product Service

CERTIFICATE

No. Q1N 17 08 68357 024

Holder of Certificate:

PENTAX
MEDICAL

HOYA Corporation

6-10-1 Nishi-shinjuku
Shinjuku-ku

Tokyo

160-0023 JAPAN



Certification Mark:



Scope of Certificate:

Design and Development, Production,
Distribution and Servicing of
Medical Endoscopes and Related Products

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). See also notes overleaf.

Report No.:

JAQ235030361

Valid from:

2018-02-01

Valid until:

2021-01-31



Date, 2018-01-26

Stefan Preiß

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CERTIFICATE**No. Q1N 17 08 68357 024****Applied Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

Facility(ies):

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, 160-0023
JAPAN

HOYA Corporation PENTAX Lifecare Division
Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo, 196-0012
JAPAN

HOYA Corporation PENTAX Lifecare Division Medical
Instrument SBU Japan Sales Headquarters
3-35-1 Shimo-renjaku, Mitaka-shi, Tokyo, 181-0013
JAPAN

HOYA Corporation PENTAX Lifecare Division
Production Technology Center / Ogawa Factory
395 Oaza-kakuyama, Ogawa-machi, Hiki-gun, Saitama,
355-0316 JAPAN

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi,
Miyagi, 987-2203 JAPAN

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012 JAPAN