



Product Service

Certificate

No. Q5 068357 0027 Rev. 00

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.:

JAQ235033920

Valid from:

2019-02-27

Valid until:

2022-02-26

Date,

2019-02-27

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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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):

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

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, 160-0023 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
Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo, 196-0012 JAPAN

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

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