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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 01

Manufacturer:

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

Product Category(ies): **Endoscopes, Ultrasound Endoscopes, their Related Equipment and Accessories (IIa, IIb)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235039944**

Valid from: **2020-01-08**
Valid until: **2024-05-26**

Digitally signed by Ceaicovschi Tudor
Date: 2024.07.16 15:43:09 EEST
Reason: MoldSign Signature
Location: Moldova

Date, **2020-01-08**

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.21 10:35:25 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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 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

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