

平成 31 年 01 月 08 日

関係各位

宣 言 書

私どもHOYA株式会社、東京都新宿区西新宿6-10-1は、添付の下記文書が書類原本の写しであることを証明致します。

「EC Certificate」

HOYA 株式会社
PENTAX ライフケア事業部
品質保証統括部 統括部長
来住 星八

January 8, 2019

To whom it may concern,

STATEMENT

We, HOYA Corporation (6-10-1 Nishi-shinjuku Shinjuku-ku, Tokyo 160-0023 Japan), hereby certify that attached document listed in above is the copy of original document.



Seiya Raiju
Vice President
Global Quality Assurance & Regulatory Affairs
PENTAX Lifecare Division
HOYA Corporation





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 068357 0029 Rev. 00

Manufacturer

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

EC-Representative:

PENTAX Europe GmbH
Julius-Vosseler-Str. 104,
22527 Hamburg,
GERMANY

Product Category(ies):

**Balloon for Ultrasound Endoscopes,
Sterile Endoscope Channel Seal for the Prevention
of Reflux of Body Fluids from Endoscopes,
Sterile Irrigation Tap for Use
in Biopsy Endoscopic Procedures**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

JAQ235034630

Valid from:

2019-02-01

Valid until:

2024-01-31

Date,

2018-12-13

Stefan Preiß



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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 068357 0029 Rev. 00

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

-/-

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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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. 00

Manufacturer:

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

EC-Representative:

PENTAX Europe GmbH
Julius-Vosseler-Str. 104,
22527 Hamburg,
GERMANY

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.:

JAQ235034630

Valid from:

2019-02-01

Valid until:

2024-01-31

Date,

2018-12-12

Stefan Preiß

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT ♦ СЕРТИФИКАТ ♦ 認證證書



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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. 00

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
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

-/-

認

証

囑託人 HOYA 株式会社 PENTAX ライフケア事業部 品質保証統括部統括部長 来住星八の代理人李振雨は、本公証人に対し来住星八が別紙証書の署名押印につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

平成 31 年 1 月 9 日、本公証人役場において

東京都立川市柴崎町 3 丁目 9 番 21 号

東京法務局所属

公証人

Notary

高

柳

輝

雄

Teruo Takayanagi

証

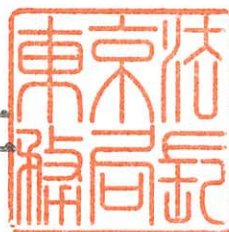
明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

平成 31 年 1 月 9 日

東京法務局長

岩山伸二



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN

This public document

2. has been signed by **Teruo Takayanagi**

3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau

4. bears the seal/stamp of **Teruo Takayanagi**, Notary

Certified

5. at Tokyo

6. JAN. 9, 2019

7. by the Ministry of Foreign Affairs

8. 19- **N9 022801**

9. Seal/stamp:

10. Signature



T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that Lee Jinwoo, an agent of Seiya Raiju, Vice President of HOYA Corporation PENTAX Lifecare Division Global Quality Assurance & Regulatory Affairs has stated in my very presence that said Seiya Raiju acknowledged himself to have signed and sealed to the attached document.

Dated this 9th day of January, 2019.



Teruo Takayanagi
Teruo Takayanagi

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU