



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

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ 認證書



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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

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