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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 068357 0031 Rev. 01

Signature Not Verified
Dokument podpisany przez Damian Juszkiewicz
Data: 2024.03.14 13:42:19 CET
Powód: Zatwierdzam dokument

Manufacturer:

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

SRN Manufacturer: **JP-MF-000005227**

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 068357 0031 Rev. 01

Report No.: **JA1828786**

Preceding Certificate No.: **G10 068357 0031 Rev. 00**

Valid from: **2022-10-20**
Valid until: **2026-08-01**

Date of Initial Issuance: **2021-08-02**

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-10-20

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
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Classification:	IIa
Device Group:	Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS
Intended Purpose:	-/-
Classification:	IIa
Device Group:	G0380 - DIGESTIVE ENDOSCOPY DEVICES - ACCESSORIES
Intended Purpose:	-/-
Classification:	IIa
Device Group:	Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	-/-
Classification:	IIa
Device Group:	Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Intended Purpose:	-/-
Classification:	IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	-/-
The validity of this certificate depends on conditions and/or is limited to the following:	Device group "Z120205" is limited to devices of MDA 0312 code.

Revision History:

Rev.	Dated	Report
00	2021-08-02	JA1601180

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