



## 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 003811 0004 Rev. 01**

### Manufacturer:

**Fabrinal SA**

Rue de la Tuilerie 42  
2300 La Chaux-de-Fonds  
SWITZERLAND

SRN Manufacturer - CH-MF-000015863

### Authorized Representative:

Veranex Germany GmbH  
Landsberger Str. 302, 80687 Munich, 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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 003811 0004 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10_003811_0004_Rev._01)

**Report No.:** ITA1880914

**Preceding Certificate No.:** G10 003811 0004 Rev. 00

**Valid from:** 2024-06-04

**Valid until:** 2028-03-08

**Date of Initial Issuance:** 2023-03-09

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-06-04



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



Product Service

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**Classification:** Class IIa  
**Device Group:** Z12129085 - VARIOUS OPHTHALMOLOGY INSTRUMENTS -  
 CONSUMABLES

**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z12120185 - OPHTHALMOLOGY ASSESSMENTS AND  
 DIAGNOSIS INSTRUMENTS - CONSUMABLES

**Intended Purpose:** -

**The validity of this certificate depends on conditions and/or is limited to the following:** -

### Revision History:

Rev.	Dated	Report	Description
00	2023-03-09	ITA1880914	Initial issuance
01	2024-06-04	ITA1880914	Amended: Editorial change of authorized representative