ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 02 03811 002

Manufacturer:

Fabrinal SA
Route de la Tuilerie 42
2300 La Chaux-de-Fonds
SWITZERLAND

Facility(ies):

Fabrinal SA
Route de la Tuilerie 42, 2300 La Chaux-de-Fonds,
SWITZERLAND

Product Category(ies):

Single use corneal electrode for electroretinography;
Ophthalmic Irrigation Cannula

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

Report No.: ITA1075602

Valid from: 2018-07-05
Valid until: 2023-07-04

04052768660084

Date, 2018-07-05

Stefan Preiß

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

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