



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 026056 0032 Rev. 00

Manufacturer: **Delta Med S.p.a.**
Via Guido Rossa 20
46019 Viadana (MN)
ITALY

SRN Manufacturer: IT-MF-000027962

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. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. 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 XI Part A 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 assurance 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:G20 026056 0032 Rev. 00

Report No.: ITA1902043

Valid from: 2023-02-02

Valid until: 2028-02-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-02-02



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No. G20 026056 0032 Rev. 00

Classification: IIa
Device Group: A010599 - OPHTHALMOLOGY INJECTION NEEDLES AND KITS
 - OTHER
 A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
 A070502 - CAPS OR OBTURATORS, PERFORABLE
 C010101 - PERIPHERAL I.V. CATHETERS

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