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

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 065346 0014 Rev. 02

Manufacturer:

INVENTIS S.r.l.
Corso Stati Uniti 1/3
35127 Padova (PD)
ITALY

SRN Manufacturer - IT-MF-000012495

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 065346 0014 Rev. 02

Report No.: ITA200220008663

Preceding Certificate No.: G10 065346 0014 Rev. 01

Valid from: 2025-02-14
Valid until: 2027-10-05

Date of Initial Issuance: 2022-10-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-14

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:	Class IIa
Device Group:	Z121401 - AUDIOMETERS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12149005 - IMPEDANCE METERS FOR THE AUDITORY SYSTEM
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12149099 - VARIOUS ENT INSTRUMENTS - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z121404 - VESTIBULAR SYSTEM ANALYSIS INSTRUMENTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12140480 - VESTIBULAR SYSTEM ANALYSIS INSTRUMENTS - HARDWARE ACCESSORIES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12140492 - VESTIBULAR SYSTEM ANALYSIS INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12149092 - VARIOUS ENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z121403 - EVOKED POTENTIAL AUDIOMETRY INSTRUMENTS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	-

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Revision History:

Rev.	Dated	Report	Description
00	2022-10-06	ITA1803262	-
01	2023-11-06	ITA2061515	Supplemented: Device(s)/group of device(s) added
02	2025-02-14	ITA200220008663	Supplemented: Device(s)/group of device(s) added

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