EU Quality Assurance Certificate

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

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Promedical AG
Bleichestrasse 65
8750 Glarus
Switzerland

has established, documented and implemented a quality assurance system in accordance with Article 10, paragraph 9 / article 22 for sterile procedure packs, of 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 conformity assessment has been carried out and successfully completed in accordance with Annex XI, Part A. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. With an exception for sterile procedure packs, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex XI,7. For devices of class III, IIb and IIa 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.

In addition to the CE marking, the identification number of the Notified Body shall be affixed by the manufacturer to the devices.

For the placing on the market of class III devices and class IIb devices an additional EU type examination certificate according to Annex X is required.

Single Registration Number of the Manufacturer (SRN):	N/A
Actor ID Number (for sterile procedure packs only):	CH-PR-000042960
Authorised Representative:	see Section 1
Limitations and Conditions:	see Section 2
List of Products, Risk Classification and Details:	see Section 3
Certificate History:	see Section 4

Certificate number:	44 910 150440	Valid from:	2026-03-02
Certification decision report No.:	3539 2820	Valid until:	2031-03-01
		First issued:	2026-03-02
		Issue date:	2026-03-02
		Edition:	1

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen, Germany
tuev-nord-cert.de
medical@tuev-nord.de

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

EU Quality Assurance Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI, Part A
Certificate number: 44 910 150440

Section 1, Authorised Representative

Company name:	N/A
Street, No.:	--
Postal Code, City:	--
Country:	--

Section 2, Limitations and Conditions

The validity of this Certificate depends on:	N/A
and the following conditions:	None
and / or is limited to the following:	N/A

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Annex XI, Part A
Certificate number: 44 910 150440

Section 3, List of Products, Risk Classification and Details

STERILE PROCEDURE PACKS ACC. ART. 22(3)

Sterilisation method:	Ethylene oxide gas sterilisation
Assessment report no.:	3539 2857
Devices or groups of devices:	Sterile Procedure Packs acc. Art. 22, 3 of Regulation (EU) 2017/745

For procedure packs placed on the market in a sterile condition acc. Art. 22,3, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to ensuring sterility until the sterile packaging is opened or damaged.

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Annex XI, Part A
Certificate number: 44 910 150440

Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2026-03-02	Initial certification	3539 2820

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