

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

biocon Medizintechnik GmbH
Triebweg 1-3
63933 Mönchberg
Germany

has established, documented and implemented a quality assurance system in accordance with Article 10, paragraph 9 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. 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 must be affixed 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):	DE-MF-000006429
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 200206	Valid from:	2026-01-26
Certification decision report no.:	3540 0887	Valid until:	2031-01-25
		First issued:	2026-01-26
		Issue date:	2026-01-26
		Edition:	1

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

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Annex XI, Part A

Certificate number: 44 910 200206

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:	--
and / or is limited to the following:	--



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Certificate number: 44 910 200206

Section 3, List of Products, Risk Classification and Details

CLASS I, DEVICES IN STERILE CONDITION

Sterilisation method: Ethylene oxide gas sterilisation (EOG)

Assessment report no.: 3540 0986

Devices or groups of devices: Patient covers and systems
Cover sheets for devices
Device slip covers
Handle covers

For class Is devices placed on the market in a sterile condition, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to the manufacture, securing and maintenance of sterile conditions.

STERILE PROCEDURE PACKS ACC. ART. 22(3)

Sterilisation method: Ethylene oxide gas sterilisation (EOG)

Assessment report no.: 3540 0888

Devices or groups of devices: Surgical sets

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 200206

Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2026-01-26	Initial certification	ZA 3540 0887

