EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

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

Belimed AG
Grienbachstrasse 11
6300 Zug
Switzerland

has established, documented and implemented a quality management 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 IX, Chapters I and III. 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 IX, Chapter I, Section 3. For devices of class 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 implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	CH-MF-000007585
Actor ID Number (for sterile procedure packs only):	N/A
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:	44 911 222305	Valid from:	2026-09-29
Certification decision report No.:	3541 4910	Valid until:	2030-07-10
		First issued:	2025-07-11
		Issue date:	2026-09-29
		Edition:	2

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 Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III
Certificate number: 44 911 222305

Section 1, Authorised Representative

Company name:	Belimed, pomivalni sistemi d.o.o.
Street, No.:	Taborska cesta 38E
Postal Code, City:	1290 Grosuplje
Country:	Slovenia

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

EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III
Certificate number: 44 911 222305

Section 3, List of Products, Risk Classification and Details

CLASS IIB

Generic device group (EMDN):	Z12011304 Medical equipment and related accessories, software and consumables – Autoclaves with a chamber larger than or equal to 1 standard sterilisation unit
TD assessment report no.:	3536 0204
Devices or groups of devices:	Sterilizer, MST-H, MST-V
Intended use:	The Belimed Medical Steam Sterilizer is intended for terminal sterilization of medical devices and accessories and other materials used in the healthcare facilities.

Generic device group (EMDN):	Z12011301 Medical equipment and related accessories, software and consumables – Cleaning and sterilisation equipment
TD assessment report no.:	--
Devices or groups of devices:	Washer Disinfector, WD 290 IQ
Intended use:	The Belimed Washer Disinfector is intended for cleaning and disinfection of medical devices and accessories.

CLASS IIA

Category of device (MDx Code)	MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation
TD assessment report no.:	3536 0207
Devices or groups of devices:	CS 750

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 Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III
Certificate number: 44 911 222305

Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2025-07-11	Initial certification	3535 9231
2	2026-09-29	Supplement of Class IIb Devices	3541 4910

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