Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.:	SX 1602324-1
Certificate Holder:	GEMÜ GmbH Seetalstr. 210 6032 Emmen Switzerland
Scope:	Design and development, clean room manufacturing and distribution of plastic injection moulded medical technology products including clean room assembly of components for medical devices. Sterile packaging and management of irradiation sterilization processes (X-Ray) for these products.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	1146193-10
Effective date:	2026-06-01
Expiry date:	2027-10-18
Issue date:	2026-06-01

Replaces certificate SX 1602324-1 issued 2024-10-10

This certificate can be validated on https://www.certipedia.com

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland® Precisely Right.

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Seetalstr. 210
6032 Emmen
Switzerland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o GEMÜ GmbH Seetalstr. 210 6032 Emmen Switzerland	Design and development, clean room manufacturing and distribution. Sterile packaging and management of irradiation sterilization processes (X-Ray).
/02	c/o GEMÜ GmbH Seetalstrasse 192 6032 Emmen Switzerland	Manufacturing and warehousing.

This certificate can be validated on https://www.certipedia.com

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