

Certificate

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

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.: 1166910-40

Effective date: 2024-10-19

Expiry date: 2027-10-18

Issue date: 2024-10-10

Replaces certificate SX 1602324-1 issued 2021-08-03.



Dr. Karsten Kluge
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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