

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1623365-1

Organization: SEM-Plastomed GmbH
Medizin- und Kunststofftechnik
Schulstr. 6
57612 Obererbach
Germany


Scope: Manufacturing and distribution of single use sterile and non-sterile medical devices, components for medical devices, as well as contract manufacturing, contract assembly and contract packaging of sterile or non-sterile medical devices or accessories.

Replaces certificate, registration no.: SX 60139983 0001

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.: 1108144-40
Effective date: 2022-10-25
Expiry date: 2025-06-11
Issue date: 2022-10-25




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