

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SEM-Plastomed GmbH
Medizin- und Kunststofftechnik
Schulstr. 6
57612 Obererbach
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design/development, production and distribution of medical
devices, components, assemblies, sets as well as contract
packaging and production of sterile OEM medical devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-06-12
Certificate Registration No.: SX 60139983 0001
An audit was performed. Report No.: 21194704 017
This Certificate is valid until: 2022-06-11

Certification Body



Date 2019-06-07



F. Bley
Dipl.-Ing. F. Bley

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60139983 0001
Report No.: 21194704 017

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

Scope:

Products included:

- sterile/non-sterile suction tubes and suction tube systems for respiration with various connectors
- sterile/non-sterile surgical suction sets and suction cannulas (Yankauer)
- sterile/non-sterile tube systems for respiration with various connectors
- sterile/non-sterile tube systems for anaesthesia with various connectors
- sterile infusion tubes/infusion tube systems
- sterile/non-sterile CO2 sampling tubes
- sterile/non-sterile adapters
- sterile/non-sterile connectors
- sterile insufflation sets
- nebulizer sets
- blood collection systems for oral surgery
- non-sterile milling discs for dental applications

Certification Body



Date: 2019-06-07



Fabian Bley
Dipl.-Ing. F. Bley