

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60130186 0001

Report No.: 21194704 014

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

Products: Medical devices for surgery, anaesthesia, respiration
and intensive care
(see attachment for products included)

Replaces Certificate, Registration No.: DD 60088706 0001

Expiry Date: 2023-06-11

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-06-12

Date: 2018-06-12



Notified Body

Fabian Bley
Dipl.-Ing. F. Bley

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60130186 0001
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Manufacturer: SEM-Plastomed GmbH
Medizin- und Kunststofftechnik
Schulstr. 6
57612 Obererbach
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Products included:

- surgical suction sets and suction cannulas (Yankauer)
- tube systems for respiration with various connectors
- tube systems for anesthesia with various connectors
- filters, air
- infusion tubes / infusion tube systems
- insufflation sets
- tubes for oxygen supply with various masks
- tubes for oxygen supply with nasal applications
- blood collection systems for oral surgery

Date: 2018-06-12



Notified Body

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LGA Products GmbH
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**Attachment to
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For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- suction tubes, suction tube systems with various connectors
- tubes for CO₂ measurement
- connectors
- adapters

Date: 2018-06-12



Notified Body

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