TÜVRheinland®

# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60128488 0001

**Report No.:** 21194311 026

**Manufacturer:**
3M Deutschland GmbH
Carl-Schurz-Str. 1
41453 Neuss
Deutschland

**Products:**
Membranes and filter for medical applications

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HD 60104385 0001

**Expiry Date:** 2023-05-06

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2018-05-07

**Date:** 2018-04-26

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

**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.

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Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** HD 60128488 0001
**Report No.:** 21194311 023

**Manufacturer:**
3M Deutschland GmbH
Carl-Schurz-Str. 1
41453 Neuss
Deutschland

Products included:

- Filter for Plasma Separation
- Filter for Plasma Fractionation
- Cytapheresis Adsorber
- Blood separation systems

Site included:

3M Deutschland GmbH
Oehder Straße 28
42289 Wuppertal
Germany

**Notified Body**

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dr. K. Kluge

**Date:** 2018-04-26