

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**DIRINCO B.V.**  
**Ketelmeer 1**  
**5347 JX Oss**  
**Netherlands**

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

**Details see attachment**

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: 2019-03-20  
Certificate Registration No.: SX 60136901 0001  
An audit was performed. Report No.: 21270380 003  
This Certificate is valid until: 2020-11-27

Certification Body



Date 2019-03-20



*D. Wiedemuth*  
Dipl.-Ing. (FH) D. Wiedemuth

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

**Attachment to  
Certificate**

**Registration No.:** SX 60136901 0001  
**Report No.:** 21270380 003

**Organization:** DIRINCO B.V.  
Ketelmeer 1  
5347 JX Oss  
Netherlands

**Scope:**

Design and development, manufacture and distribution of anticoagulants based on sterile trisodium citrate solutions for use as catheter lock.  
Distribution, installation and servicing of medical devices in the field of hemodialysis and blood treatment.

**Certification Body**



**Date:** 2019-03-20

  
**Dipl.-Ing. (FH) D. Wiedemuth**