EC Certificate

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

Registration No.: HD 60124779 0001

Report No.: 21270380 001

Manufacturer:
DIRINCO B.V.
Ketelmeer 1
5347 JX Oss
Netherlands

Products:
Anticoagulant for use as catheter lock

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60102260 0001

Expiry Date: 2022-11-27

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: 2017-11-28

Date: 2017-11-24

Notified Body

Roland Gruber

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 60124779 0001
Report No.: 21270380 001

Manufacturer: DIRINCO B.V.
Ketelmeer 1
5347 JX Oss
Netherlands

Products included:

Anticoagulant, antimicrobial and reducing biofilm formation for use as catheter lock
- CitraLock 30% and 46,7%
- 5 ml in Polyethylene vials

Anticoagulant for use as catheter lock CitraLock 4%
- 5 ml in Polyethylene vials

Notified Body

Date: 2017-11-24

Roland Gruber

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle