EC Certificate

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

Registration No.: HD 60139484 0001

Report No.: 17042992 010

Manufacturer:

Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
Bandar Sultan Sulaiman
42000 Pelabuhan Klang, Selangor Darul Ehsan
Malaysia

Digitally signed by Talpiş Andrei
Date: 2021.04.17 07:54:48 EEST
Reason: MoldSign Signature
Location: Moldova

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60124195 0001

Expiry Date: 2024-05-27

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: 2019-08-07

Date: 2019-08-07

Notified Body

Fuxiu Sheng

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 60139484 0001
Report No.: 17042992 010

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Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
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42000 Pelabuhan Klang, Selangor Darul Ehsan
Malaysia

Products:

Tubing Sets for Hemodialysis, Disposable AV Fistula Needle Sets, Disposable AV Fistula Needle Sets (Dull Needle series), Disposable AV Fistula Needle Sets (Safety Needle series), Hollow Fiber Dialyzers, Plasmafilters, Tubing Sets for Blood Purification, Hemofilters, Hemodialysis Bicarbonate

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-07