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

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.

Digitally signed by Talpiș Andrei
Date: 2024.01.11 14:44:21 EET
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

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

Manufacturer:
Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
Bandar Sultan Sulaiman
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

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Vital Healthcare Sdn. Bhd.
PT 83718, Jalan Bestari 1A/KU7,
Taman Perindustrian Kapar Bestari,
42200 Kapar, Selangor
Malaysia

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 21, 2023

Application for: QMS

Certificate No. : HD 60139484 0001
Requirement : Directive 93/42/EEC
Confirmation letter ID : DOC_2023-04-18_ HD 60139484 0001
Report no. : 10922427-100

Dear Madame or Sir,

Update of information to Certificate no. HD 60139484 0001, issued on 07.08.2019

The change notification received on 27.06.2022 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).
With this document we would like to confirm the following updated information to the afore mentioned certificate

Add location address:
LOT 83718, JALAN BESTARI 1A/ KU 7, KAWASAN INDUSTRI HI-TECH, SUNGAI KAPAR INDAH, 42200 KAPAR, MUKIM KAPAR, DAERAH KLANG, SELANGOR DARUL EHSAN, MALAYSIA

Best regards,

Samuel Qin

Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 21, 2023

Vital Healthcare Sdn. Bhd.
PT 83718, Jalan Bestari 1A/KU7,
Taman Perindustrian Kapar Bestari,
42200 Kapar, Selangor
Malaysia

Application for: QMS

Certificate No. : HD 60139484 0001
Requirement : Directive 93/42/EEC
Confirmation letter ID : DOC_2023-04-18_ HD 60139484 0001
Report no. : 10922427-100

Dear Madame or Sir,

Update of information to Certificate no. HD 60139484 0001, issued on 07.08.2019

The change notification received on 23.03.2023 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).
With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address:	Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia
New Manufacturer address:	PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari, 42200 Kapar, Selangor, Malaysia

Revised location address

Old location address:	LOT 83718, JALAN BESTARI 1A/ KU 7, KAWASAN INDUSTRI HI-TECH, SUNGAI KAPAR INDAH, 42200 KAPAR, MUKIM KAPAR, DAERAH KLANG, SELANGOR DARUL EHSAN, MALAYSIA
New location address:	Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

Best regards,

Samuel Qin

Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety