

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

**Design and Development, Manufacture  
and Distribution of Medical Devices  
(see attachment for products included)**

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: 2017-12-27  
Certificate Registration No.: SX 60124196 0001  
An audit was performed. Report No.: 17042992 004  
This Certificate is valid until: 2020-12-25

Certification Body



Date 2017-12-27



**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 60124196 0001  
**Report No.:** 17042992 004

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

**Scope:**

**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

**Certification Body**



**Date:** 2017-12-27

