

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2135836-1

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

Scope: Design and Development, Manufacture and Distribution of 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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10917191-310
Effective date: 2020-12-26
Expiry date: 2023-12-25
Issue date: 2020-12-23



A blue ink signature is written over a circular stamp. The stamp contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'TÜVRheinland'.
Herbert Zhong
TÜV Rheinland LGA Products GmbH
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