

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2135836-1

Certificate Holder: Vital Healthcare Sdn. Bhd.
PT 83718, Jalan Bestari 1A/KU7,
Taman Perindustrian Kapar Bestari,
42200 Kapar, Selangor
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.: 10922511-100

Effective date: 2023-12-26

Expiry date: 2026-12-25

Issue date: 2023-12-04

Replaces certificate SX 2135836-1 issued 2023-04-18

This certificate can be validated on <https://www.certipedia.com>



Samuel Qin
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Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Vital Healthcare Sdn. Bhd. PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari, 42200 Kapar, Selangor Malaysia	Aspects related to Design and Development, Manufacturing and Distribution
/02	c/o Vital Healthcare Sdn. Bhd. Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia	Aspects related to Manufacturing

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