

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2053735-1

Organization:

Comcorde Medical (M) S/B

1, Jln 11/32B,

TSI Business Industrial Park, Bt 6.5 off Jln Kepong,

52000 Kuala Lumpur

Malaysia

Scope:

Manufacture and distribution of infusion related Disposables, including: Infusion Sets & Accessories, Disposable Armboard, Luer Lock Stopper, Non-Conductive Connecting Tube, Suction Pre-Filter Kit, Suction Yankauer, Suction Connecting Tubes & Accessories, Syringe Adaptors-Transfer Sets, Transducer Protector Urinary/ Nelaton Catheter, UW2000 Underwater Chest Drainage System, Bladder Irrigation Set, Needle Free Valve, TPN Bags & Accessories, Spinal Manometer, Snap Pin Seal, Extension Tubes, Syringe Pump Tubes & Accessories, 3way Stopcock With/Without Extension Tube, Drainage Bottle, Bacterial / Viral Filter With / Without HME, Leukocyte Filter With/Without Bag, Heart Lung Tubing Pack, Vacuum Cup, CVPM, Pressure Monitoring Sampling Line, Ryles Tube / Enteral Feeding Tube, Nasal Cannula, Pressure Monitoring Kit With Transducer (CDPM), Urine Bag, Nipple & Nut, Thoracic Catheter/ Trocar,

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Arthroscopy Set, IV Cannula, Close System Transfer Device.

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.:

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TÜVRheinland III

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