

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2160467-1

Organization: Fleming Medical Ltd
Suit 1126, 11/F, Ocean Centre,
Harbour City, 5 Canton Road,
Tsim Sha Tsui, Kowloon,
Hong Kong

Scope: Design and Development, Manufacture and Distribution of Silicone Foam Dressings, Hydrophilic-Gel Exudate- Absorbent Dressings, Sterile Burn Geis, Foam Dressings, Absorbent Dressings;
Manufacture and Distribution of Absorbent Cotton Wools, Adhesive Bandages, Alginate Dressings, Bandages, Blood Pressure Monitors, Catheterization Packs /Catheter Packs, Compressor Nebulizers, Cooling Patches, Cold and hot therapy mat/pad/packs, Digital Thermometers, Electronic Non-invasive Sphygmomanometers, First Aid Kits, Gauze Type, Hydrocolloid Bandages, Infrared Ear Thermometers with & without Probe Cover, Instant Cold Packs, Instant Hot Packs and Hot Packs, Kinesiology Tapes, Medical Compression Stockings, Medical Supports, Medical Tapes, Natural Heating Physical Therapeutic Plasters, Natural Latex and Synthetic Medical Examination Gloves (Powdered and Powder-free), Nebulizers, Nebulizer Masks, Non-woven Types, Non-woven Adhesive Wound Dressings, Non-Sterile Nebulizer Kit including nebulizer bottle, mouth-piece, air tube, nose piece, mask, Plasters, Sterile Disposable Dressing Packs and Procedure Packs, Sterile solution in unidose containers, Sterile Transparent Semipermeable Dressings, Sterile Wound Dressings, Skin Closure Strips, Transparent Island Dressings, Pulse Oximeters, Warmers

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.: 244348884-200
Effective date: 2021-11-09
Expiry date: 2024-09-17
Issue date: 2021-11-09



TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2160467-1

Organization: Fleming Medical Ltd
Suit 1126, 11/F, Ocean Centre,
Harbour City, 5 Canton Road,
Tsim Sha Tsui, Kowloon,
Hong Kong

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Fleming Medical Ltd Room 605, Senben Building, No. 567 Tianyaoqiao Road, Xuhui District, 200030 Shanghai P.R. China	Design and Development, Manufacture and Distribution of the a.m. products

Report No.: 244348884-200
Effective date: 2021-11-09
Expiry date: 2024-09-17
Issue date: 2021-11-09



Jason Pan

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany