

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

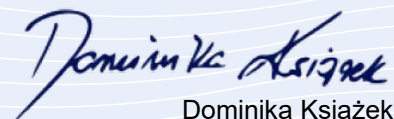
Registration No.: SX 2293555-1
Certificate Holder: Fleming Medical Ltd
Dock Road
Limerick
V94 K6W4
Ireland

Scope: Design and development, manufacture and distribution of class I medical devices for Wound Care and Support Products. Distribution and storage of sterile and non-sterile medical devices for wound care, continence care, diagnostics and patient monitoring, patient emergencies, respiratory tract infections, user joints and muscles support, hot and cold therapy, therapy and fixation, disinfection and medical personal protection. Distribution and storage of medical devices for drug storage and furniture medical device. Service of medical devices for patient monitoring and patient emergencies.

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.: 111129758 60
Effective date: 2025-04-01
Expiry date: 2028-03-31
Issue date: 2025-03-28
Replaces certificate SX 2293555-1 issued 2022-04-01

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



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