

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1032296-1

Certificate Holder: Nipro Medical Europe NV
Blokhuisstraat 42
2800 Mechelen
Belgium

Scope: Design and development, distribution, labelling and packaging of sterile and non-sterile medical devices for renal care, infusion therapy, general hospital supplies, and (cardio)vascular care

Labelling, packaging, and distribution of in vitro diagnostics devices for diabetes care

Installation and service of dialysis machines, pure water treatment systems, and (cardio)vascular imaging systems

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.: 1179979-100

Effective date: 2025-03-02

Expiry date: 2028-03-01

Issue date: 2025-02-28

Replaces certificate SX 1032296-1 issued 2024-12-17



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