MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C546025-NA-DNK

Initial certification date:
11 October 2022

Valid:
09 April 2023 – 08 April 2026

This is to certify that the management system of

ArcRoyal

Virginia Road, Kells, Co. Meath, Ireland

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Manufacture, sales and distrubution of Sterile Pressure Monitoring Lines, Introducer Needles, Inflation Device, Administration Sets and Accessories, Manifolds, Control Syringes, Light Handle Covers, Tip Cleaners, Skin Markers and Procedure Packs, and following non-sterile medical devices: Light Handle Covers, Tip Cleaners, Skin Markers.

Place and date:
Høvik, 05 April 2023

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

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Management Representative