

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C546025

Initial certification date:
11 October 2022

Valid:
22 April 2026 – 08 April 2029

This is to certify that the management system of

ArcRoyal

Virginia Road, Kells, 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 distribution of Introducer Needles, 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, 22 April 2026



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

Cecilie Gudesen Torp

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Management Representative