

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
ISO 14385

Initial certification date:  
11 October 2022

Valid:  
09 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, 09 April 2026



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

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative