

# MANAGEMENT SYSTEM CERTIFICATE

Site certificate No.:  
C838412-1

Valid:  
13 March 2026 – 30 April 2028

Belongs to main certificate number:  
C838412

This is to certify that the centrally implemented management system for

## DeRoyal Industries, Inc. - Royal Sterilization Systems

1135 Highway 33 South, New Tazewell, TN, 37825, USA

and the sites as mentioned in the appendix accompanying this certificate

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 site scope:

**Management, Warehouse, Quality Assurance, Quality Control, Ethylene oxide sterilization services of medical devices. The validation and routine control of a sterilization process as per ISO 11135:2014 requirements and laboratory services for chemistry, microbiology, sterility and media preparation.**

Place and date:  
Høvik, 13 March 2026



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

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative

## Appendix to Certificate

### DeRoyal Industries, Inc. - Royal Sterilization Systems

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DeRoyal Industries, Inc. - Royal Sterilization Systems	1135 Highway 33 South, New Tazewell, TN, 37825, USA	Management, Warehouse, Quality Assurance, Quality Control, Ethylene oxide sterilization services of medical devices. The validation and routine control of a sterilization process as per ISO 11135:2014 requirements and laboratory services for chemistry, microbiology, sterility and media preparation.
DeRoyal Industries, Inc. - Royal Sterilization Systems	1211 Highway 33 South, New Tazewell, TN, 37825, USA	Management, Warehouse, Quality Assurance, Quality Control, Ethylene oxide sterilization services of medical devices. The validation and routine control of a sterilization process as per ISO 11135:2014 requirements and laboratory services for chemistry, microbiology, sterility and media preparation.

