

NEMIUS Group GmbH

Berliner Straße 116, 63065 Offenbach, Germany

This is a multi-site certificate. Additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

DS/EN ISO 13485:2016

Scope of application

Consulting services in medical device regulatory affairs, quality assurance and quality management systems. Provision of normative and regulatory services for companies in the medical technology and healthcare industry. Services as Quality Management representative, European authorised representative, Safety officer and Person responsible for regulatory compliance for legal manufacturers of medical devices and in-vitro diagnostics.

Original cycle start date:

27-February-2019

Expiry date of previous cycle:

NA

Certification/Recertification Audit date:

NA

Certification/ Recertification cycle start date:

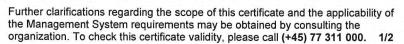
27-February-2022

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 26-February-2025

Certificate No.: DNKFRC102219 Version: 1 Revision date: 23-February-2022

Certification Office:

Bureau Veritas Certification Denmark A/S Oldenborggade 25-31, 7000 Fredericia, Denmark









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Site Name/location:	Site Addition Date:	Site Address:	Site Scope:
NEMIUS Group GmbH (Head Office)	27-February- 2019	Berliner Straße 116, 63065 Offenbach, Germany	Consulting services in medical device regulatory affairs, quality assurance and quality management systems. Provision of normative and regulatory services for companies in the medical technology and healthcare industry. Services as Quality Management representative, European authorised representative, Safety officer and Person responsible for regulatory compliance for legal manufacturers of medical devices and in-vitro diagnostics.
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