BUREAU VERITAS

Bureau Veritas Certification

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

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call **(+45) 77 311 000.**

DANAK
SYSTEM Reg.nr. 5005

Bureau Veritas Certification

NEMIUS Group GmbH

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.

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.
NEMIUS Medical GmbH & Co. KG	23-February-2022	Berliner Straße 116, 63065 Offenbach, Germany	

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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DANAK SYSTEM Reg.nr. 5005