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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 011765 0048 Rev. 00

Manufacturer:

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560 JAPAN

SRN Manufacturer: **JP-MF-000019022**

Authorized Representative:

NIHON KOHDEN EUROPE GmbH
Raiffeisenstrasse 10, 61191 Rosbach, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 011765 0048 Rev. 00

Report No.: **JN1779131**

Valid from: **2022-08-24**

Valid until: **2027-08-23**

Christoph Dicks
Head of Certification/Notified Body

Issue date: **2022-08-24**

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. V12 011765 0048 Rev. 00

Classification:	**B**
Device Group:	**W0202 - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS**
Intended Purpose:	**IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers**
Classification:	**C**
Device Group:	**W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)**
IVP Code:	**IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays**
Intended Purpose:	**IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease**
Classification:	**B**
Device Group:	**W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY**
Intended Purpose:	**IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers**
Classification:	**B**
Device Group:	**W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)**
Intended Purpose:	**IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers**
The validity of this certificate depends on conditions and/or is limited to the following:	**- none -**

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