ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 001541 0004 Rev. 01

Manufacturer:

EXIAS Medical GmbH
Kratkystraße 2
8020 Graz
AUSTRIA

SRN Manufacturer - AT-MF-000024050

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation 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 and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 001541 0004 Rev. 01

Report No.:	713334497
Preceding Certificate No.:	V74 001541 0004 Rev. 00
Valid from:	2024-07-19
Valid until:	2029-02-06
Date of Initial Issuance:	2024-02-07

Marta Carnielli
Head of Certification IVD

Issue date: 2024-07-22

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

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

TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 001541 0004 Rev. 01

Classification: Class B
Device Group: W010106 - CLINICAL CHEMISTRY - RAPID TESTS & POC
Basic UDI-DI: 912012727e1-CartridgeVF

Intended Purpose:
The EXIAS e|1 Cartridge is a multi-use in-vitro diagnostic medical device consumable used in combination with the EXIAS e|1 Analyzer intended to quantitatively measure the electrolytes Sodium (Na+), Potassium (K+), ionized Calcium (Ca2+) and Chloride (Cl-) as well as pH and Hematocrit (Hct) in human whole blood, serum, plasma, undiluted urine and aqueous solutions. The device is dedicated to aid in diagnosis of patients in laboratories and Point-of-Care (POC) environments and is intended for professional use only.

Device(s):
EXIAS e|1 Cartridge 100
Ref. No.: M000944
EXIAS e|1 Cartridge 100 oQC
Ref. No.: M000945
EXIAS e|1 Cartridge 150
Ref. No.: M000338
EXIAS e|1 Cartridge 150 oQC
Ref. No.: M000339
EXIAS e|1 Cartridge 300
Ref. No.: M000137
EXIAS e|1 Cartridge 300 oQC
Ref. No.: M000138
EXIAS e|1 Cartridge 600
Ref. No.: M000139
EXIAS e|1 Cartridge 600 oQC
Ref. No.: M000140

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

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

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 001541 0004 Rev. 01

Classification:	Class B
Device Group:	W010106 - CLINICAL CHEMISTRY - RAPID TESTS & POC
Basic UDI-DI:	912012727e1-QC2S
Intended Purpose:	The EXIAS e|1 QC Quality Control material is an assayed multi analyte quality control material used for manual quality control measurements to monitor the performance of the EXIAS e|1 Cartridge in combination with the EXIAS e|1 Analyzer for the analytes Sodium (Na+), Potassium (K+), ionized Calcium (Ca2+), Chloride (Cl-), pH and Hematocrit (Hct). The device is dedicated for the use in laboratories and Point-of-Care (POC) environments and is intended for professional use only. It is not intended to be used with devices from other manufacturers.
Device(s):	EXIAS e|1 QC-1 Quality Control Ref. No.: M000293 EXIAS e|1 QC-2 Quality Control Ref. No.: M000294 EXIAS e|1 QC-3 Quality Control Ref. No.: M000295

-

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-07	713276663_TD	Initial issuance
01	2024-07-19	713334497	Supplemented: Device(s)/group of device(s) added

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

TÜV®