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EU Declaration of Conformity

of the EXIAS e|1 Cartridge

according to Annex IV of Regulation 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices.

EXIAS Medical GmbH herewith declares, that the **EXIAS e|1 Cartridge**, an in vitro diagnostic medical device, is in conformity with *Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017* and with *Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.*

According to rule 6 of Annex VIII of Regulation (EU) 2017/746 the EXIAS e|1 Cartridge is a class B in vitro diagnostic medical device.

This declaration of conformity is issued under the sole responsibility of EXIAS Medical GmbH.

Manufacturer

EXIAS Medical GmbH
Kratkystraße 2
8020 Graz – Austria
SRN (EU - Single Registration Number): AT-MF-000024050

Related Product(s)

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 (Ca^{2+}) 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.

The **EXIAS e|1 Cartridge** is available in 8 different types intended for maximum 100, 150, 300 or 600 sample measurements and with or without on-board Quality Control included.

Catalogue No.	Product name	Basis UDI-DI [1]	EMDN-Code[2]
M000944	EXIAS e|1 Cartridge 100	912012727e1-CartridgeVF	W0101060605
M000945	EXIAS e|1 Cartridge 100 oQC	912012727e1-CartridgeVF	W0101060605
M000338	EXIAS e|1 Cartridge 150	912012727e1-CartridgeVF	W0101060605
M000339	EXIAS e|1 Cartridge 150 oQC	912012727e1-CartridgeVF	W0101060605
M000137	EXIAS e|1 Cartridge 300	912012727e1-CartridgeVF	W0101060605
M000138	EXIAS e|1 Cartridge 300 oQC	912012727e1-CartridgeVF	W0101060605
M000139	EXIAS e|1 Cartridge 600	912012727e1-CartridgeVF	W0101060605
M000140	EXIAS e|1 Cartridge 600 oQC	912012727e1-CartridgeVF	W0101060605

[1] Basis UDI-DI: " Basic Unique Device Identifier acc. Annex VI (Part C) of Regulation (EU) 2017/746

[2] EMDN-Code: European Medical Device Nomenclature Code for Registration in the European Database for Medical Devices (EUDAMED)

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Validity

This declaration of conformity is valid from **19.07.2024** and will cease to be valid with the issue of a new declaration of conformity or withdrawal.

Conformity Assessment

Conformity Route:	Technical Document Assessment Class B/C/D for Near-Patient Testing - Annex IX
Certificates:	EU Technical Documentation Assessment Certificate (IVDR): No. V74 001541 0004 Rev. 01 EU Quality Management System Certificate (IVDR): No. V10 001541 0003 Rev. 00

Notified Body Information

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany
Identification no.:	0123

Place and date of issue: Graz, 01. AUG. 2024

On behalf of EXIAS Medical

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