EU Declaration of Conformity

of the **EXIAS e|1 Cartridge**

according to Annex III of Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 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 the *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices* 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 Annex II of Directive 98/79/EC the EXIAS e|1 Cartridge is classified as a "general 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 for the use in laboratories and Point-of-Care (POC) environments and is intended for professional use only.

The **EXIAS e|1 Cartridge** is available in 6 different types (to which this certificate refers) intended for maximum 150 or 300 or 600 sample measurements and with or without on-board Quality Control included.

Catalogue No.	Product name	EMDN-Code[1]
M000338	EXIAS e|1 Cartridge 150	W0101060605
M000339	EXIAS e|1 Cartridge 150 oQC	W0101060605
M000137	EXIAS e|1 Cartridge 300	W0101060605
M000138	EXIAS e|1 Cartridge 300 oQC	W0101060605
M000139	EXIAS e|1 Cartridge 600	W0101060605
M000140	EXIAS e|1 Cartridge 600 oQC	W0101060605

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

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Date: 2023.03.02 10:07:27 EET
Reason: MoldSign Signature
Location: Moldova

EXIAS Medical GmbH
Kratkystraße 2
8020 Graz, Austria
FN 426693s
Tel.: +43 (0) 316 922953
office@exias-medical.com
www.exias-medical.com

Validity

This declaration of conformity is valid from **25 May, 2022** and will cease to be valid with the issue of a new declaration of conformity or withdrawal.

Place and date of issue: Graz, 25. MAI 2022

On behalf of EXIAS Medical

EXIAS MEDICAL Kratkystraße 2, 8020 Graz

Gerald Nauschnegg, General Manager

Josef Hindinger, General Manager

Udo Klinger, Quality and Compliance Manager

EXIAS Medical GmbH
Kratkystraße 2
8020 Graz, Austria
FN 426693s
Tel.: +43 (0) 316 922953
office@exias-medical.com
www.exias-medical.com