

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 (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 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

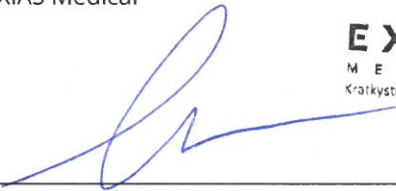
¹ EMDN-Code: European Medical Device Nomenclature Code for Registration in the European Database for Medical Devices (EUDAMED)

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.

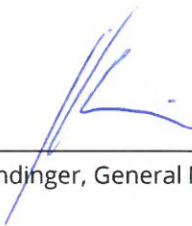
Place and date of issue: Graz, 25. MAI 2022

On behalf of EXIAS Medical



Gerald Nauschnegg, General Manager

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