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Location: Moldova

EU Declaration of Conformity

of the EXIAS e|1 Analyzer

according to Annex IV of Regulation 2017/746 of the European Parliament and of the council of 5 April 2017.

EXIAS Medical GmbH herewith declares, that the **EXIAS e|1 Analyzer**, an in-vitro diagnostic medical device, is in conformity with the *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 5b of Annex VIII of Regulation (EU) 2017/746 the EXIAS e|1 Analyzer is a class A 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 Analyzer** is a fully automated in-vitro diagnostic medical device used in combination with the multi-use consumable **EXIAS e|1 Cartridge** 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.

Catalogue No.	Product name	Basic UDI-DI [1]	EMDN-Code[2]	Software Vers.
M000204	EXIAS e|1 Analyzer	912012727e1-AnalyzerJG	W0201040201	3.00

[1] Basic 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 **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

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