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Location: Moldova

EU Declaration of Conformity

of the EXIAS e|1 QC Quality Control

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 QC Quality Control**, 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 QC Quality Control 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 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 (Ca^{2+}), Chloride (Cl^-), pH and Hematocrit (Hct).

The device is dedicated for the use in laboratories and Point-of-Care (POC) environments. It is intended for professional use only. It is not intended to be used with devices from other manufacturers.

The **EXIAS e|1 QC Quality Control** material is available in three different types (levels), providing low, medium and high concentrations of the analytes.

Catalogue No.	Product name	EMDN-Code[1]
M000293	e|1 QC-1 Quality Control	W010106040201
M000294	e|1 QC-2 Quality Control	W010106040201
M000295	e|1 QC-3 Quality Control	W010106040201

*... EMDN = European Medical Device Nomenclature

[1] 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
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