

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Max-Planck-Ring 21 65205 Wiesbaden · Germany

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### **AUTHORIZATION LETTER**

We, HUMAN Gesellschaft für Biochemica und Diagnostica mbH (hereinafter called "HUMAN"), Max - Planck - Ring 21, 65205 Wiesbaden, Germany, hereby certify that company

"Echipamed Plus" SRL Valea Trandafirilor 24 <B>, 2001 Chisinau Moldova

is our exclusive representative for HUMAN / IMTEC products in the territory of Moldova.

Echipamed Plus is therefore authorized to import, stock, market and sell HUMAN labeled products throughout the territory of Moldova.

Echipamed Plus is also fully authorized to participate in official tenders and to provide installation, warranty service and maintenance for HUMAN equipment in the territory of Moldova.

Echipamed Plus is further authorized to submit applications on our behalf to the competent authority of Moldova for the registration and re-registration of HUMAN-labeled products in the name of HUMAN.

This Authorization Letter remains valid until 31.12.2025 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 06 January 2025

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

André Jendretzki

International Sales Manager

Human

Gesellschaft für Biochemica und Diagnostica mbH Max-Planck-Ring 21 65205 Wiesbaden-Delkenheim Germany

> www.human.de Mail: human@human.de



For electronic distribution only Nur zur elektronischen Verbreitung

## Certificate

We hereby certify the company

Human Gesellschaft für Biochemica und Diagnostica mbH Max-Planck-Ring 21 65205 Wiesbaden Germany



with the sites listed in the attachment the introduction and application of a

#### Quality management system according to EN ISO 9001

in the scope

development, manufacturing and distribution of in vitro diagnostic devices and associated analyzers as well as laboratory devices and distribution of pipettes

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015 Quality management systems - Requirements

Valid from 2025-03-12

Valid until 2028-03-11

Registration No. D1030000090

P23-01546-284931 Report No.

Stuttgart, 2025-03-10

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01



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# Certificate

We hereby certify the company

Human Gesellschaft für Biochemica und Diagnostica mbH Max-Planck-Ring 21 65205 Wiesbaden Germany



with the sites listed in the attachment the introduction and application of a

#### Quality management system according to EN ISO 13485

in the scope

development, manufacturing and distribution of reagents, reagent products, calibrators and control materials for clinical chemistry, haematology, haemostasis, immune chemistry as well as analyzers for in-vitro diagnosis and the distribution of test kits for molecular biology analyses as well as rapid tests for the diagnosis of infectious diseases

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Valid from 2025-03-12 Valid until 2028-03-11 Registration No. D1030000091 Report No. P23-01546-284935

Stuttgart, 2025-03-10

Certification Body

DAKKS
Deutsche
Akkreditierungsstelle
D-ZM-16002-06-00