Human

Gesellschaft für Biochemica
und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden · Germany

Telefon +49 6122 9988-0
Telefax +49 6122 9988-100

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 31.12.2021 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 26 January 2021
HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Dhimitraq Jani
International Sales Manager

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

Digitally signed by Iurchevici Valeriu
Date: 2021.07.07 18:23:42 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate

mdc medical device certification GmbH
certifies that

Human

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

with the location

Stegelitzer Straße 3
39126 Magdeburg

for the scope

development, manufacturing and distribution of in vitro diagnostic products and analyzers

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2019-03-12
Valid until	2022-03-11
Registration no.	D1030000073
Report no.	P18-01225-128829
Stuttgart	2019-03-01

Head of Certification Body

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

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Human
Diagnostics Worldwide

Konformitätserklärung

Wir,
HUMAN Gesellschaft für Biochemica und Diagnostica mbH (HUMAN GmbH) erklären hiermit in eigener Verantwortung, dass auf der Basis unseres Qualitätsmanagement-Systems (DIN EN ISO 9001:2008 und DIN EN ISO 13485:2003 + AC:2007) das/die nachstehende/en Produkt/e

HUMALYTE PLUS^3, HUMALYTE PLUS^5
Art.Nr.: 17470/10, 17470/20
Klassifizierung: Sonstiges in-vitro Diagnosticum (IVD)

ein Konformitätsbewertungsverfahren gemäß den Anforderungen der Richtlinie/n

98/79/EG (Anhang III)

und anwendbarer Normen durchlaufen haben und die Konformität bestätigt wurde.

Als sichtbarer Nachweis der Konformität trägt/tragen das/die Produkt/e das Zeichen

Declaration of Conformity

We,
HUMAN Gesellschaft für Biochemica und Diagnostica mbH (HUMAN GmbH) herewith declare under our sole responsibility that based upon our quality management system (DIN EN ISO 9001:2008 and DIN EN ISO 13485:2003+AC:2007) the following product/s

HUMALYTE PLUS^3, HUMALYTE PLUS^5
Cat.Nos.: 17470/10, 17470/20
Classification: Other in vitro diagnostic device (IVD)

has/have passed a conformity assessment process according to the requirements of directive/s

98/79/EC (Annex III)

and applicable standards and that conformity has been confirmed.

As visible proof of conformity the product/s is/are labeled with the sign

CE

HUMAN GmbH

Dr. Torsten Börchers
Director Quality Assurance

Wiesbaden, 15.06.2011

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eMail: human@human.de;
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