

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 ,
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.

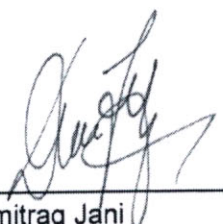
Echipamed Plus is also fully authorized to participate in official tenders and to provide installation, warranty service and maintenance for HUMAN equipment in the territory of Moldova.

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-Deikheim
Germany



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

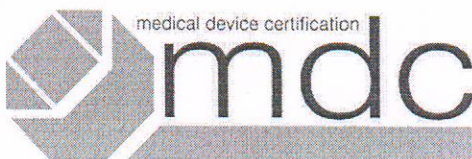
EN ISO 13485

**Medical devices – Quality management systems –
Requirements for regulatory purposes**

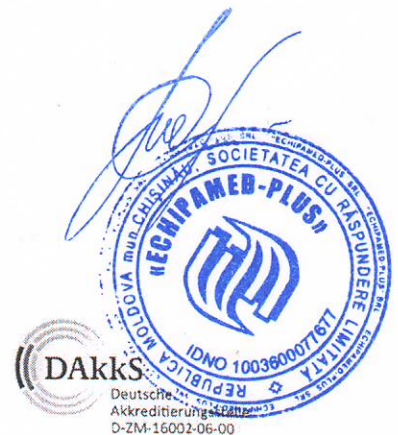
EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

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



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>



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 PLUS³, HUMALYTE PLUS⁵

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 PLUS³, HUMALYTE PLUS⁵

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



HUMAN GmbH

Dr. Torsten Borchers
Director Quality Assurance

Wiesbaden, 15.06.2011