Human

Gesellschaft für Biochemica
und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden · Germany

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

Digitally signed by Iurchevici Valeriu
Date: 2021.07.23 16:27:04 EEST
Reason: MoldSign Signature
Location: Moldova

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

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 9001

Quality management systems – Requirements

(ISO 9001:2015)

Valid from	2019-03-12
Valid until	2022-03-11
Registration no.	D1030000072
Report no.	P18-01225-128826
Stuttgart	2019-03-01

Head of Certification Body

medical device certification mdc

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

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

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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

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Konformitätserklärung

Wir,
HUMAN Gesellschaft für Biochemica und Diagnostica mbH (HUMAN), Max-Planck-Ring 21, 65205 Wiesbaden, Deutschland
erklären hiermit in eigener Verantwortung, dass auf der Basis unseres Qualitätsmanagement Systems (EN ISO 9001:2008 und EN ISO 13485:2012 + AC:2012) die nachstehenden Produkte

Name (Art.-Nr.)
HumaScope Light^{LED} (14400)
HumaScope Classic^{LED} (14500)
HumaScope Advanced^{LED} (14600)
HumaScope Advanced^{LED} Trinocular (14601)
HumaScope Premium^{LED} (14700)
HumaScope Premium^{LED} Trinocular (14701)

Klassifizierung: elektrisch betriebenes Gerät

ein Konformitätsbewertungsverfahren gemäß den Anforderungen der Richtlinien

2014/35/EC,
2014/30/EC

und folgenden anwendbaren Normen

EN 61010-1:2010,
EN 55011:2009+A1:2010
EN 61000-3-2:2014, EN 61000-3-3:2013
EN 61326-1:2013

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), Max-Planck-Ring 21, 65205 Wiesbaden, Deutschland herewith declare under our sole responsibility that based upon our quality management system (EN ISO 9001:2008 and EN ISO 13485:2012 + AC:2012) the following products

Name (Cat. No.)
HumaScope Light^{LED} (14400)
HumaScope Classic^{LED} (14500)
HumaScope Advanced^{LED} (14600)
HumaScope Advanced^{LED} Trinocular (14601)
HumaScope Premium^{LED} (14700)
HumaScope Premium^{LED} Trinocular (14701)

Classification: electrically operated devices

have passed a conformity assessment process according to the requirements of directives

2014/35/EC,
2014/30/EC

and the following applicable standards

EN 61010-1:2010,
EN 55011:2009+A1:2010
EN 61000-3-2:2014, EN 61000-3-3:2013
EN 61326-1:2013

and that conformity has been confirmed.

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

CE

HUMAN Gesellschaft für Biochemica
und Diagnostica mbH

Wiesbaden, 2016-11-03

Dr. Torsten Börchers
Vice President Quality Assurance & Regulatory Affairs