Digitally signed by Iurchevici Valeriu
Date: 2021.11.05 18:37:33 EET
Reason: MoldSign Signature
Location: Moldova

ORIGINAL

To whom it may concern

Manufacturer's Authorization

Date: January 04, 2021

We Boditech Med Inc., who are official manufacturers of the ichroma and the AFIAS products, having factories at 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gang-won-do, Korea 200-883, do hereby declare that

ECHIPAMED PLUS SRL
str. Valea Trandafirilor 24 "B", of. 80
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for the ichroma and the AFIAS products of Boditech Med Inc., in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of the ichroma and the AFIAS products, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2021.

Boditech Med Inc.

Hye-sung Kim
Sales manger

43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, South Kore
Boditech Med Inc.
Eui yul choi
PRESIDENT EUI YUL CHOI

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 053112 0026 Rev. 00

Holder of Certificate: **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do 24398
REPUBLIC OF KOREA

Facility(ies):
Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398, REPUBLIC OF KOREA

Boditech Med Inc.
14, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398, REPUBLIC OF KOREA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Medical Devices - Reagents and Instruments for Point of Care Testing(POCT)**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74954566

Valid from: 2019-11-01
Valid until: 2022-10-31

Date, 2019-10-15

Stefan Preiß
Head of Certification/Notified Body

"ECHIPAMED-PLUS"

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS D-Dimer Cat. No. : SMFP-4
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:	ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, May 10, 2018
Signature:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS Ferritin Cat. No. : SMFP-23
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:	ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, September 11, 2017
Signature:	Eyulchoi **Dr. Eui Yul Choi / CEO**

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS COVID-19 Ab Cat. No. : SMFP-72
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied:	EN ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, March 24, 2020

Signature:

Dr. Eui Yul Choi / CEO

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Incorporated 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398 REPUBLIC OF KOREA
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS CRP Cat. No. : SMFP-2
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:	ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, May 10, 2018

Signature:

Dr. Eui Yul Choi / CEO

REPUBLICA MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea
European Representative:	OBELIS S.A Bd. Général Wahis 53, 1030 Brussels, Belgium
Product:	AFIAS COVID-19 nAb Cat. No. : SMFP-82
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied:	EN ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011
Place, Date of Issue:	Chuncheon, Korea, January 14, 2021

Signature:

Dr. Eui Yul Choi / CEO

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373