Digitally signed by Iurchevici Valeriu
Date: 2025.10.23 12:11:58 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

To whom it may concern

Manufacturer's Authorization

Date: *January 6, 2025*

We *Boditech Med Inc.*, who are official manufacturers of *AFIAS products*, having factories at *43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, Korea, 24398*, do hereby declare that

"ECHIPAMED-PLUS" SRL
str. Valea Trandafirilor 24 "B", of. 2-7
MD-2001, Chisinau
Republic of Moldova

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

We declare that above mentioned company is authorized to do registration, quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of *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 31.12.2025.

Boditech Med Inc.

Hye-sung Kim
Sales manager

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

"ECHIPAMED-PLUS" SOCIETATEA CU RĂSPUNDERE LIMITATĂ
REPUBLICA MOLDOVA mun. CHIȘINĂU IDNO 1003600077677

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD
Product Service

Certificate

No. Q5 053112 0026 Rev. 02

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.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), Nucleic acid testing including Detection of Infectious Diseases and nucleic acid extraction**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 053112 0026 Rev. 02

Report No.: 74963667, 74963667_CN

Valid from: 2022-11-01
Valid until: 2025-10-31

Date, 2022-10-28

Christoph Dicks
Head of Certification/Notified Body

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD
Product Service

Certificate

No. Q5 053112 0026 Rev. 02

Applied Standard(s):

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

Facility(ies):

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

Design, Development, Production and Distribution of In Vitro Diagnostic Medical Devices-Reagents and instruments for Point of Care Testing (POCT), Nucleic acid testing including Detection of Infectious Diseases and Nucleic Acid Extraction

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

Warehouse Instruments for Point of Care Testing (POCT), Nucleic acid testing including Detection of Infectious Diseases and Nucleic Acid Extraction

Boditech Med Inc.
48, Geodudanji 2-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398, REPUBLIC OF KOREA

Production and final inspection of Instruments for Point of Care Testing (POCT), Nucleic acid testing including Detection of Infectious Diseases and Nucleic Acid Extraction

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

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boditech BIO TECHNOLOGY

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
Classification:	Others (Neither listed in the annex II of the IVDD, Non-self-testing device) List B (to Annex II of the IVDD)
Conformity Assessment Route:	Self-Declaration Route According to the Annex III of the IVDD According to the Annex IV without sections 4 and 6 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 24, 2022
Signature:	Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, Republic of Korea T:+82-33-243-1400 F:+82-33-243-9373

Dr. Eui Yul Choi / CEO

REPUBLICA MOLDOVA mun. CHISINAU. SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077671

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DECLARATION OF CONFORMITY

PRODUCT

Catalog Number	Classification	Product name
SMFP-9	List B	AFIAS PSA
SMFP-2	Others	AFIAS CRP
SMFP-3	Others	AFIAS Total β-hCG
SMFP-4	Others	AFIAS D-Dimer
SMFP-5	Others	AFIAS FSH
SMFP-6	Others	AFIAS LH
SMFP-7	Others	AFIAS PCT
SMFP-8	Others	AFIAS PRL
SMFP-20	Others	AFIAS TSH
SMFP-13	Others	AFIAS CK-MB
SMFP-28	Others	AFIAS HbA1c
SMFP-19	Others	AFIAS T4
SMFP-18	Others	AFIAS T3
SMFP-23	Others	AFIAS Ferritin
SMFP-27	Others	AFIAS AFP
SMFP-21	Others	AFIAS CEA
SMFP-29	Others	AFIAS Testosterone
SMFP-30	Others	AFIAS Microalbumin
SMFP-22	Others	AFIAS Cortisol
SMFP-34	Others	AFIAS Myoglobin
SMFP-35	Others	AFIAS Tn-I Plus
SMFP-36	Others	AFIAS NT-proBNP
SMFP-25	Others	AFIAS ROTA
SMFP-26	Others	AFIAS NORO
SMFP-43	Others	AFIAS Rota/Adeno
SMFP-32	Others	AFIAS PCT Plus
SMFP-59	Others	AFIAS Cardiac Triple
SMFP-63	Others	AFIAS Vitamin D
SMFP-62	Others	AFIAS AMH
SMFP-38	Others	AFIAS TSH Plus
SMFP-59	Others	AFIAS Cardiac Triple
SMFP-63	Others	AFIAS Vitamin D

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Republic of KOREA
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DECLARATION OF CONFORMITY

SMFP-62	Others	AFIAS AMH
SMFP-52	Others	AFIAS β-hCG Plus
SMFP-53	Others	AFIAS FSH Plus
SMFP-67	Others	AFIAS Anti-CCP Plus
SMFP-70	Others	AFIAS ST2
SMFP-54	Others	AFIAS LH Plus
SMFP-55	Others	AFIAS PRL Plus
SMFP-72	Others	AFIAS COVID-19 Ab
SMFP-74	Others	AFIAS IL-6
SMFP-77	Others	AFIAS COVID-19 Flu/Ag Combo
SMFP-75	Others	AFIAS Infliximab
SMFP-76	Others	AFIAS Total Anti-Infliximab
SMFP-82	Others	AFIAS COVID-19 nAb
SMFP-83	Others	AFIAS BNP
SMFP-95	Others	AFIAS Troponin T
SMFP-99	Others	AFIAS IGRA-TB
SMFP-94	Others	AFIAS Progesterone
SMFP-84	Others	AFIAS Total IgE
SMFP-96	Others	AFIAS Free Anti-Trastuzumab
SMFP-86	Others	AFIAS Free Anti-Infliximab
SMFP-90	Others	AFIAS Golimumab
SMFP-87	Others	AFIAS Free Anti-Adalimumab
SMFP-78	Others	AFIAS hsCRP
SMFP-107	Others	AFIAS COVID-19 Ag
SMFP-103	Others	AFIAS COVID-19 SP/NP IgG
SMFP-89	Others	AFIAS Adalimumab

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