

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, Gangwon-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.

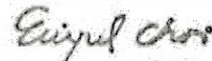
Boditech Med Inc.



Hye-sung Kim
Sales manager

43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, South Korea

Boditech Med Inc.



PRESIDENT EUI YUL CHOI



Boditech Med Inc. www.boditech.co.kr

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, KOREA

바디텍메드(주) 강원특별자치도 춘천시 동내면 가두단지 1길 43 (24398) Tel +82-33-243-1400 Fax +82-33-243-9373



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:



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





DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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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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

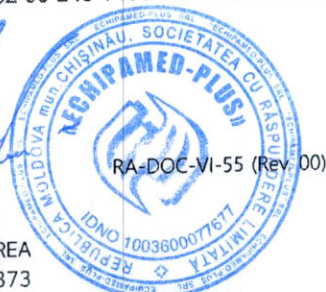
Place, Date of Issue:

Chuncheon, Korea, January 24, 2022

Signature:

Eui Yul Choi
Dr. Eui Yul Choi / CEO

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, 24398, Republic of Korea
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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

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



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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



RA-DOC-VI-55 (Rev. 00)

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