

ORIGINAL

To whom it may concern

Manufacturer's Authorization

Date: January 2, 2024

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 31.12.2024.

Boditech Med Inc.



Hye-sung Kim
Sales manager

Boditech Med Inc.

43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, South Korea 200-883
T: +82-33-243-1400 F: +82-33-243-9373



Boditech Med Inc. www.boditech.co.kr

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, KOREA
바디텍메드(주) 강원특별자치도 춘천시 동내면 거두단지 1길 43 (24398) Tel +82-33-243-1400 Fax +82-33-243-9373



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:



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



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:

Eyul Choi
 Dr. Eui Yul Choi / CEO

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 Chuncheon-si, Gangwon-do, 24398, Republic of Korea
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RA-DOC-VI-55 (Rev. 00)

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43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Republic of KOREA
 바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

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 |



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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