

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.

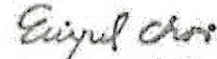
Boditech Med Inc.



Hye-sung Kim
Sales manager

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

Boditech Med Inc.



PRESIDENT EUI YUL CHOI



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:

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

Boditech Med Inc. www.boditech.co.kr

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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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)

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.

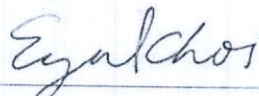
Standards applied:

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 24, 2023

Signature:



Dr. Eui Yul Choi / CEO

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Chuncheon-si, Gangwon-do, 24398, Republic of Korea
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Boditech Med Inc.
Euiyul choi
PRESIDENT EUI YUL CHOI



DECLARATION OF CONFORMITY

PRODUCT

| Catalog Number | Classification | Product name |
|----------------|----------------|-------------------------------------|
| CFPO-309 | Others | Boditech Adalimumab Control |
| CFPO-315 | Others | Boditech Anti-Adalimumab Control |
| CFPO-300 | Others | Boditech Anti-Infliximab Control |
| CFPO-313 | Others | Boditech Anti-Trastuzumab control |
| CFPO-120 | Others | Boditech ASO Calibrator |
| CFPO-119 | Others | Boditech ASO Control |
| CFPO-311 | Others | Boditech AST Control |
| CFPO-304 | Others | Boditech BNP Control |
| CFPO-305 | Others | Boditech BNP Calibrator |
| CFPO-211 | Others | Boditech Calprotectin Control |
| CFPO-205 | Others | Boditech Cardiac Triple Calibrator |
| CFPO-204 | Others | Boditech Cardiac Triple Control |
| CFPO-312 | Others | Boditech Cholesterol control |
| CFPO-303 | Others | Boditech COVID-19 nAb Control |
| CFPO-281 | Others | Boditech Dengue IgG/IgM Calibrator |
| CFPO-280 | Others | Boditech Dengue IgG/IgM Control |
| CFPO-283 | Others | Boditech Dengue NS1 Ag Calibrator |
| CFPO-282 | Others | Boditech Dengue NS1 Ag Control |
| CFPO-310 | Others | Boditech Golimumab Control |
| CFPO-222 | Others | Boditech H. pylori Ag Control |
| CFPO-14 | Others | Boditech iFOB Neo Control |
| CFPO-221 | Others | Boditech iFOB/Calprotectin Control |
| CFPO-294 | Others | Boditech IGRA-TB Control |
| CFPO-296 | Others | Boditech IL-6 Control |
| CFPO-297 | Others | Boditech IL-6 Calibrator |
| CFPO-299 | Others | Boditech Infliximab Control |
| CFPO-165 | Others | Boditech NORO Control |
| CFPO-264 | Others | Boditech Progesterone Calibrator |
| CFPO-238 | Others | Boditech Progesterone Control |
| CFPO-301 | Others | Boditech Quick™ COVID-19 Ag Control |

Boditech Med Inc. www.boditech.co.kr

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RA-DOC-VI-53 (Rev. 00)

DECLARATION OF CONFORMITY

| | | |
|----------|--------|-------------------------------------|
| CFPO-302 | Others | Boditech Quick™ COVID-19 Ab Control |
| CFPO-115 | Others | Boditech RF IgM Calibrator |
| CFPO-103 | Others | Boditech RF IgM Control |
| CFPO-210 | Others | Boditech Syphilis Control |
| CFPO-267 | Others | Boditech Tn-I Calibrator |
| CFPO-241 | Others | Boditech Tn-I Control |
| CFPO-219 | Others | Boditech Total IgE Control |
| CFPO-306 | Others | Boditech Troponin T Control |
| CFPO-307 | Others | Boditech Troponin T Calibrator |
| CFPO-314 | Others | Boditech Toxo IgG/IgM Control |
| CFPO-106 | Others | Boditech Tumor marker Calibrator |
| CFPO-94 | Others | Boditech Tumor marker Control |
| CFPO-114 | Others | Boditech Vitamin D Calibrator |
| CFPO-102 | Others | Boditech Vitamin D Control |
| CFPO-4 | Others | Boditech MAU Control |
| CFPO-95 | Others | Boditech Hormone Control |
| CFPO-107 | Others | Boditech Hormone Calibrator |
| CFPO-100 | Others | Boditech CRP Control |
| CFPO-112 | Others | Boditech CRP Calibrator |
| CFPO-96 | Others | Boditech HbA1c Control |
| CFPO-108 | Others | Boditech HbA1c Calibrator |
| CFPO-97 | Others | Boditech PCT Control |
| CFPO-109 | Others | Boditech PCT Calibrator |
| CFPO-99 | Others | Boditech Ferritin Control |
| CFPO-111 | Others | Boditech Ferritin Calibrator |
| CFPO-98 | Others | Boditech Cardiac Control |
| CFPO-110 | Others | Boditech Cardiac Calibrator |
| CFPO-101 | Others | Boditech D-Dimer Control |
| CFPO-94 | Others | Boditech Tumor marker Control |
| CFPO-113 | Others | Boditech D-Dimer Calibrator |
| CFPO-106 | Others | Boditech Tumor marker Calibrator |
| CFPO-170 | Others | Boditech ROTA Control |
| CFPO-102 | Others | Boditech Vitamin D Control |

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DECLARATION OF CONFORMITY

| | | |
|----------|--------|----------------------------------|
| CFPO-213 | Others | Boditech Tn-I Plus Control |
| CFPO-212 | Others | Boditech Tn-I Plus Calibrator |
| CFPO-223 | Others | Boditech PCT Plus Calibrator |
| CFPO-225 | Others | Boditech PCT Plus Control |
| CFPO-260 | Others | Boditech LH Calibrator |
| CFPO-234 | Others | Boditech LH Control |
| CFPO-271 | Others | Boditech NT-proBNP Calibrator |
| CFPO-245 | Others | Boditech NT-proBNP Control |
| CFPO-270 | Others | Boditech Myoglobin Calibrator |
| CFPO-244 | Others | Boditech Myoglobin Control |
| CFPO-269 | Others | Boditech CK-MB Calibrator |
| CFPO-243 | Others | Boditech CK-MB Control |
| CFPO-257 | Others | Boditech FSH Plus Calibrator |
| CFPO-231 | Others | Boditech FSH Plus Control |
| CFPO-265 | Others | Boditech Testosterone Calibrator |
| CFPO-239 | Others | Boditech Testosterone Control |
| CFPO-252 | Others | Boditech PRL Calibrator |
| CFPO-226 | Others | Boditech PRL Control |
| CFPO-254 | Others | Boditech TSH Calibrator |
| CFPO-228 | Others | Boditech TSH Control |
| CFPO-255 | Others | Boditech TSH Plus Calibrator |
| CFPO-229 | Others | Boditech TSH Plus Control |
| CFPO-259 | Others | Boditech hCG Plus Calibrator |
| CFPO-233 | Others | Boditech hCG Plus Control |
| CFPO-262 | Others | Boditech Cortisol Calibrator |
| CFPO-236 | Others | Boditech Cortisol Control |
| CFPO-261 | Others | Boditech LH Plus Calibrator |
| CFPO-235 | Others | Boditech LH Plus Control |
| CFPO-266 | Others | Boditech T3 Calibrator |
| CFPO-240 | Others | Boditech T3 Control |
| CFPO-256 | Others | Boditech FSH Calibrator |
| CFPO-230 | Others | Boditech FSH Control |
| CFPO-108 | Others | Boditech hCG Calibrator |

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BA-DCL-VI-53 (Rev. 00)

DECLARATION OF CONFORMITY

| | | |
|----------|--------|--------------------------------|
| CFPO-96 | Others | Boditech hCG Control |
| CFPO-253 | Others | Boditech PRL Plus Calibrator |
| CFPO-227 | Others | Boditech PRL Plus Control |
| CFPO-263 | Others | Boditech T4 Calibrator |
| CFPO-237 | Others | Boditech T4 Control |
| CFPO-272 | Others | Boditech CEA Calibrator |
| CFPO-246 | Others | Boditech CEA Control |
| CFPO-274 | Others | Boditech AFP Calibrator |
| CFPO-248 | Others | Boditech AFP Control |
| CFPO-165 | Others | Boditech NORO Control |
| CFPO-164 | Others | Boditech Rota/Adeno Control |
| CFPO-215 | Others | Boditech AMH Calibrator |
| CFPO-214 | Others | Boditech AMH Control |
| CFPO-288 | Others | Boditech Anti-CCP Plus Control |
| CFPO-289 | Others | Boditech ST2 Control |
| CFPO-290 | Others | Boditech ST2 Calibrator |
| CFPO-292 | Others | Boditech COVID-19 Ab Control |
| CFPO-293 | Others | Boditech COVID-19 Ag Control |

