



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

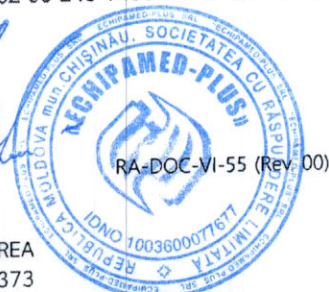
Place, Date of Issue:

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
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, 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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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

Manufacturer:

Boditech Med Incorporated
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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)

Conformity Assessment Route:

Self-Declaration Route According to the Annex III of the IVDD

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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:

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
T:+82-33-243-1400 F:+82-33-243-9373

Boditech Med Inc.
Eui Yul Choi
PRESIDENT EUI YUL CHOI



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
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

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바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373



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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43, Geodudanji 1-gil, Dongnae-myeon, Chungcheong-si, Gangwon-do, 200-863, Republic of KOREA
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

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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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바디텍메드(주) 강원도 춘천시 동내면 거두난지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373



BA-PDCE-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

