ORIGINAL

Digitally signed by Iurchevici Valeriu
Date: 2023.03.28 15:32:58 EEST
Reason: MoldSign Signature
Location: Moldova

To whom it may concern

## Manufacturer's Authorization

Date: January 2, 2023

We Boditech Med Inc., who are official manufacturers of the ichroma and the 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. 80
MD-2001, Chisinau
Republic of Moldova

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

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform installation and after sales service of the ichroma and the 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 31.12.2023.

Boditech Med Inc.

*Hye-sung Kim*
*Sales manger*

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

SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003800077677 REPUBLICA MOLDOVA mun. CHIŞINĂU

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

TÜV®


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

# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS CRP<br>Cat. No. : SMFP-2 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, May 10, 2018 |

Signature:

Dr. Eui Yul Choi / CEO

REPUBLICA MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677



**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, 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<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS D-Dimer<br>Cat. No. : SMFP-4 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, May 10, 2018 |
| Signature: | Eui Yul Choi<br>**Dr. Eui Yul Choi / CEO** |



**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
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# DECLARATION OF CONFORMITY

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|---|---|
| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS PCT<br>Cat. No. : SMFP-7 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, September 11, 2017 |

Signature:

Eyul Choi

**Dr. Eui Yul Choi / CEO**



**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
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# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Inc.<br>43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,<br>Gang-won-do, 24398, Republic of Korea |
| European Representative: | OBELIS S.A.<br>Bd. Général Wahis 53, 1030 Brussels, Belgium |
| Product: | AFIAS PSA<br>Cat. No. : SMFP-9 |
| Classification: | List B acc. TO Annex II of IVDD Directive |
| Conformity Assessment Route: | 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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,<br>EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Notified No. | TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 Munich · Germany<br>(NB No. : 0123) |
| Certificate No. | V1 053112 0030 Rev.00 (Valid until: 2024-05-06) |
| Place, Date of Issue: | Chuncheon, Korea, May 20, 2022 |

Signature:

Eyul choi

Dr. Eul Yul Choi / CEO

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, KOREA
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# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Inc.<br>43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,<br>Gang-won-do, 24398, Republic of Korea |
| European Representative: | OBELIS S.A.<br>Bd. Général Wahis 53, 1030 Brussels, Belgium |
| Product: | AFIAS TSH<br>Cat. No. : SMFP-20 |
| Classification: | Others<br>(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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,<br>EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, May 20, 2022 |
| Signature: | Eyulchoi<br>**Dr. Eui Yul Choi / CEO** |

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, KOREA
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# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS HbA1c<br>Cat. No. : SMFP-28 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2012, EN13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, October 16, 2018 |
| Signature: | Eui Yul Choi<br>Dr. Eui Yul Choi / CEO |

"ECHIPAMED-PLUS" IDNO 1003600077677

**Boditech Med Inc.** www.boditech.co.kr
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# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Inc.<br>43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,<br>Gang-won-do, 24398, Republic of Korea |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53, 1030 Brussels, Belgium |
| Product: | AFIAS T4<br>Cat. No. : SMFP-19 |
| Classification: | Others<br>(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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,<br>EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, May 20, 2022 |
| Signature: | Eyul Choi<br>**Dr. Eui Yul Choi / CEO** |

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, KOREA
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# DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer: | Boditech Med Inc.<br>43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si,<br>Gang-won-do, 24398, Republic of Korea |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53, 1030 Brussels, Belgium |
| Product: | AFIAS T3<br>Cat. No. : SMFP-18 |
| Classification: | Others<br>(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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,<br>EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, May 20, 2022 |

Signature:

Dr. Eui Yul Choi / CEO

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, KOREA
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

# DECLARATION OF CONFORMITY

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| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS Ferritin<br>Cat. No. : SMFP-23 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, September 11, 2017 |
| Signature: | Eyulchoi<br>**Dr. Eui Yul Choi / CEO** |

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

# DECLARATION OF CONFORMITY

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| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS Myoglobin<br>Cat. No. : SMFP-34 |
| 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.

| | |
|---|---|
| Standards applied: | ISO 15223-1:2016, EN ISO 13485:2012, EN 13612:2002,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, September 11, 2017 |
| Signature: | Eui Yul Choi<br>**Dr. Eui Yul Choi / CEO** |



**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korea
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# DECLARATION OF CONFORMITY

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| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | AFIAS Tn-I Plus<br>Cat. No. : SMFP-35 |
| 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,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, September 17, 2019 |

Signature:

Dr. Eui Yul Choi / CEO

REPUBLICA MOLDOVA, SOCIETATEA CU RASPUNDERE LIMITATA "TECHIPAMED-PLUS" IDNO 1003600077677

**Boditech Med Inc.** www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea
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# DECLARATION OF CONFORMITY

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| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398.<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>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,<br>EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012,<br>EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011,<br>EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, January 24, 20 |
| 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

Boditech Med Inc.
PRESIDENT EUI YUL CHOI

REGISTRAMED-PLUS
IDNO 1002600077677

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

# 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 |

RA-DOC-VI-53 (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

| | | |
|---|---|---|
| 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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# 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 |

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