



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

Product: AFIAS Total β hCG
 Cat. No. : SMFP-3

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,
 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, September 11, 2017

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

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

Product: AFIAS D-Dimer
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,
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, May 10, 2018

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

RA-DOC-II-33 (Rev. 05)

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

Product:

AFIAS FSH
Cat. No. : SMFP-5

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,
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, May 10, 2018

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

RA-DOC-II-34 (Rev. 06)

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

Product: AFIAS LH
 Cat. No. : SMFP-6

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,
 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, September 11, 2017

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

RA-DOC-II-35 (Rev. 05)

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

Product: AFIAS PCT
Cat. No. : SMFP-7

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

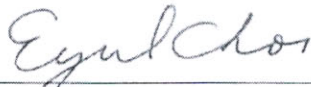
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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,
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, September 11, 2017

Signature:


Dr. Eui Yul Choi / CEO



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

Product: AFIAS PRL
 Cat. No. : SMFP-8

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,
 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, September 11, 2017

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

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

Product: AFIAS Ferritin
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,
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, September 11, 2017

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

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

Product: AFIAS Testosterone
 Cat. No. : SMFP-29

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,
 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, September 11, 2017

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

RA-EGC-II-99 (Rev. 02)

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

Product: AFIAS Cortisol
Cat. No. : SMFP-22

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, 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, May 10, 2018

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



RA-DOC-11-61 (Rev. 03)

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

Product: AFIAS Tn-I Plus
 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,
 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, September 17, 2019

Signature: 
 Dr. Eui Yul Choi / CEO



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

Product: AFIAS NT-proBNP
 Cat. No. : SMFP-36

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,
 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, December 3, 2018

Signature: 
 Dr. Eui Yul Choi / CEO



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

Product: AFIAS Cardiac Triple
 Cat. No. : SMFP-59

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,
 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, April 27, 2018

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

RA-DOC-II-111 (Rev. 00)

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

Product: AFIAS Vitamin D
 Cat. No. : SMFP-63

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, September 25, 2019

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

RA-DOC-II-112 (REV. 01)

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

Product: AFIAS COVID-19 Ab
 Cat. No. : SMFP-72

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, March 24, 2020

Signature:

Eui Yul 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, Republic of Korea
 바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

RA-DOC-163 Rev. 00

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

Product: AFIAS COVID-19 Ag
 Cat. No. : SMFP-71

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

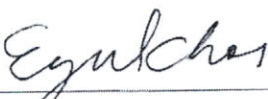
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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, June 1, 2020

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

RA-DOC-II-165 (Rev. 00)

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

Product: AFIAS IL-6
 Cat. No. : SMFP-74

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

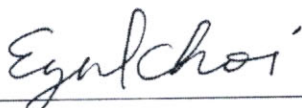
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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, August 24, 2020

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

RA-DOC-II-168 (Rev. 00)

DECLARATION OF CONFORMITY

Manufacturer: Boditech Med Inc.
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

Product: AFIAS COVID-19 nAb
Cat. No. : SMFP-82

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 14, 2021

Signature: 
Dr. Eui Yul Choi / CEO



DECLARATION OF CONFORMITY

Manufacturer: Boditech Med Inc.
 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

Product: AFIAS BNP
 Cat. No. : SMFP-83

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, March 4, 2021

Signature: 
 Dr. Eui Yul Choi / CEO



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

Product: Boditech PCT Control
 Cat. No. : CFPO-97

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, August 13, 2019

Signature:


 Dr. Eui Yul Choi / CEO



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

Product: Boditech Ferritin Control
 Cat. No. : CFPO-99

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

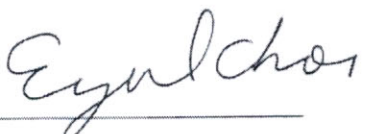
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, July 17, 2019

Signature:



 Dr. Eui Yul Choi / CEO



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

Product: Boditech Cardiac Control
 Cat. No. : CFPO-98

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, July 17, 2019

Signature: 
 Dr. Eui Yul Choi / CEO



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

Product: Boditech D-Dimer Control
 Cat. No. : CFPO-101

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

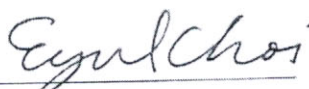
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:


 Dr. Eui Yul Choi / CEO



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

Product: Boditech Tn-I Plus Control
 Cat. No. : CFPO-212

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

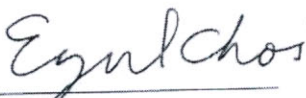
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:



 Dr. Eui Yul Choi / CEO



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

Product: Boditech LH Control
 Cat. No. : CFPO-234

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, September 30, 2019

Signature:


 Dr. Eui Yul Choi / CEO



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

Product: Boditech Testosterone Control
Cat. No. : CFPO-239

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:


Dr. Eui Yul Choi / CEO



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

Product: Boditech Testosterone Control
Cat. No. : CFPO-239

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:


Dr. Eui Yul Choi / CEO

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

Product: Boditech PRL Control
 Cat. No. : CFPO-226

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

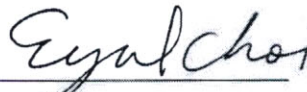
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:



Dr. Eui Yul Choi / CEO



RA-DOCN-68 (Rev001)

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

Product: Boditech Cortisol Control
 Cat. No. : CFPO-236

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:


 Dr. Eui Yul Choi / CEO



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

Product: Boditech FSH Control
 Cat. No. : CFPO-230

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:



Dr. Eui Yul Choi / CEO



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

Product: Boditech hCG Control
 Cat. No. : CFPO-232

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

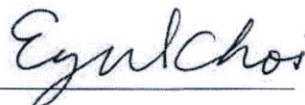
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, October 23, 2019

Signature:



Dr. Eui Yul Choi / CEO



RA-DO-01-90 (Rev. 01)

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

Product: Boditech COVID-19 Ab Control
 Cat. No.: CFPO-292

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, May 27, 2020

Signature:



 Dr. Eui Yul Choi / CEO



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

Product: Boditech COVID-19 Ag Control
 Cat. No.: CFPO-293

Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

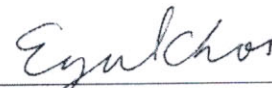
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, June 1, 2020

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

RA-2020-III-0115 (Rev. 00)

DECLARATION OF CONFORMITY

Manufacturer: Boditech Med Inc.
 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

Product: Boditech COVID-19 nAb Control
 Cat. No. : CFPO-303

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 ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, January 14, 2021

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

RA-DOC-III-123 (Rev.00)