

ORIGINAL

To whom it may concern

### Manufacturer's Authorization

Date: January 04, 2021

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 200-883, 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.

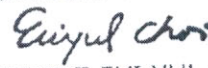
This authorization letter will remain valid until 31.12.2021.

Boditech Med Inc.

  
Hye-sung Kim  
Sales manger

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

Boditech Med Inc.

  
PRESIDENT EUI YUL CHOI

Boditech Med Inc. [www.boditech.co.kr](http://www.boditech.co.kr)

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea  
비디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373





Product Service

# Certificate

No. Q5 053112 0026 Rev. 00

**Holder of Certificate: Boditech Med Inc.**43, Geodudanji 1-gil, Dongnae-myeon  
Chuncheon-si, Gang-won-do 24398  
REPUBLIC OF KOREA**Facility(ies):**Boditech Med Inc.  
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398, REPUBLIC OF KOREABoditech Med Inc.  
14, 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)****Applied Standard(s):**EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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). See also notes overleaf.

**Report No.:** 74954566**Valid from:** 2019-11-01**Valid until:** 2022-10-31**Date,** 2019-10-15Stefan Preiß  
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 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](http://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. 001

# 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](http://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)

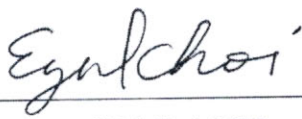
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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](http://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 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](http://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 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



# 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](http://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  
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.

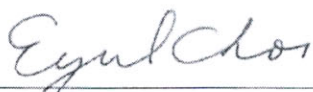
Standards applied:

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

**Boditech Med Inc.** [www.boditech.co.kr](http://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-36 (Rev. 04)

# 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 CRP  
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,  
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](http://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-31 (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 Tn-I  
Cat. No. : SMFP-12

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

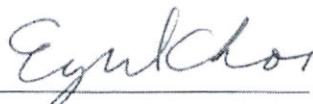
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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](http://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-47 (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 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.

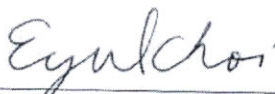
Standards applied:

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

**Boditech Med Inc.** [www.boditech.co.kr](http://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-74 (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 Myoglobin  
Cat. No. : SMFP-34

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

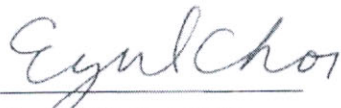
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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,  
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](http://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-63-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 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](http://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:** 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

**Boditech Med Inc.** [www.boditech.co.kr](http://www.boditech.co.kr)

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea  
비디텍메드(주) 강원도 춘천시 동내면 기도단지 1길 43 Tel 102 33 243 1400 Fax 102 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: Boditech COVID-19 Ag Control  
Cat. No.: CFPO-293

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

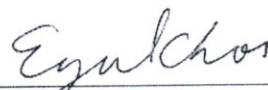
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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](http://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





# 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 Vitamin D Control  
Cat. No. : CFPO-102

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 25, 2019

Signature:

  
Dr. Eui Yul Choi / CEO

**Boditech Med Inc.** [www.boditech.co.kr](http://www.boditech.co.kr)

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RA-DOC-III-43 (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 D-Dimer Control  
Cat. No. : CFPO-101

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

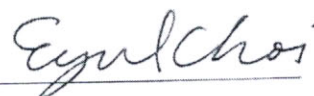
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 Ferritin Control  
Cat. No. : CFPO-99

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

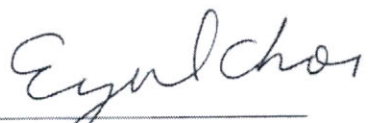
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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

**Boditech Med Inc.** [www.boditech.co.kr](http://www.boditech.co.kr)

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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

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

**Boditech Med Inc.** [www.boditech.co.kr](http://www.boditech.co.kr)

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea  
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RA-DOC-1929A (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: Boditech CRP Control  
Cat. No. : CFPO-100

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

**Boditech Med Inc.** [www.boditech.co.kr](http://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-W-20 (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: Boditech Tn-I Plus Control  
Cat. No. : CFPO-212

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

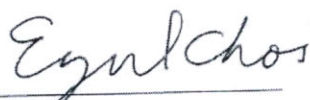
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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

Boditech Med Inc. [www.boditech.co.kr](http://www.boditech.co.kr)

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RA-DOC-11045 (Rev. 01/18)



# 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 NT-proBNP Control  
Cat. No. : CFPO-245

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.

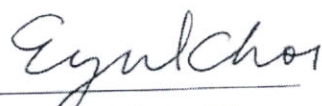
Standards applied:

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

Boditech Med Inc. [www.boditech.co.kr](http://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



# 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 Myoglobin Control  
Cat. No. : CFPO-244

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.

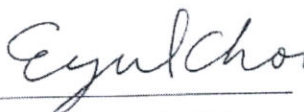
Standards applied:

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-DOC-III-28 (Rev. 02)