

ORIGINAL

To whom it may concern

**Manufacturer's Authorization**

Date: December 23, 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 24398, do hereby declare that

ECHIPAMED PLUS SRL  
 str. Valea Trandafirilor 24 "B", of. 80  
 MD-2001, Chisinau  
 Republic of Moldova

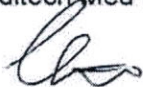
is our official distributor and local representative for the ichroma and the AFIAS products of Boditech Med Inc., in the territory of the Republic of Moldova.

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 31.12.2022.

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, 200-883, Republic of KOREA  
 바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT



Product Service

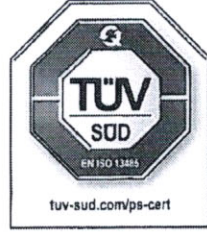
# Certificate

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 KOREA  
  
Boditech 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,** 2019-10-15

Stefan 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 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

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 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  
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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 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 CK-MB  
 Cat. No. : SMFP-13

**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  
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RA-DOC-II-48 (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 HbA1c  
 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:   
 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

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 AFP  
Cat. No. : SMFP-27

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-57 (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 CEA  
 Cat. No. : SMFP-21

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

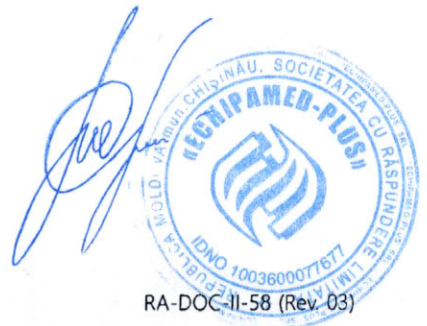
**Conformity Assessment Route:** Self-Declaration Route According to the Annex III of the IVDD

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 NT-proBNP  
 Cat. No. : SMFP-36

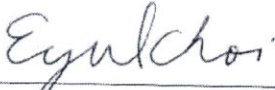
Classification: Others (Neither listed in the annex II of the IVDD, Non-self-testing device)

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 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:   
 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 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  
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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



# 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 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



# 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 HbA1c Control  
 Cat. No. : CFPO-96

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

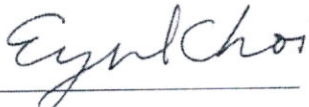
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 Ferritin Control  
 Cat. No. : CFPO-99

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

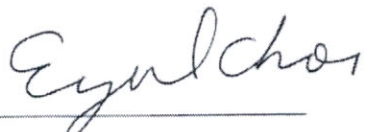
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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 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 CEA Control  
 Cat. No. : CFPO-246

**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



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

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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:** Boditech AFP Control  
 Cat. No. : CFPO-248

**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 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:**

  
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 Dr. Eui Yul Choi / CEO



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

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RA-DOC-RE-114 (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 Ag Control  
Cat. No.: CFPO-293

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

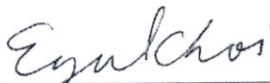
Conformity Assessment Route: Self-Declaration Route According to the Annex III of the IVDD

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:

  
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Dr. Eui Yul Choi / CEO



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# 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

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