ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Date: 2023.01.09 18:20:35 EET
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Location: Moldova

TÜV SÜD Product Service

Certificate

No. Q5 053112 0026 Rev. 02

Holder of Certificate: **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do 24398
REPUBLIC OF KOREA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Medical Devices - Reagents and Instruments for Point of Care Testing (POCT), Nucleic acid testing including Detection of Infectious Diseases and nucleic acid extraction**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 053112 0026 Rev. 02

Report No.: 74963667, 74963667_CN

Valid from: 2022-11-01
Valid until: 2025-10-31

Date, 2022-10-28

Christoph Dicks
Head of Certification/Notified Body

"TECHPARTED-PLUS" IDNO 1003600077677 REPUBLICA MOLDOVA

TÜV®

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

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 βhCG 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:	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, 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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

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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 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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"ECHIPAMED-PLUS" SOCIETATEA CU RĂSPUNDERE LIMITATĂ
IDNO 1003600077677

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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 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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"ECHIPAMED-PLUS" IDNO 1003600077677

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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:

Eyul Choi

Dr. Eui Yul Choi / CEO

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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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"SCHIPAMED-PLUS" IDNO 1003600077677

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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 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:	Eyulchoi **Dr. Eui Yul Choi / CEO**

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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:	Eyul Choi **Dr. Eui Yul Choi / CEO**

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

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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 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

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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 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

REPUBLICA MOLDOVA MUN. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHIPAMED-PLUS" IDNO 1003600077677

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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 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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"TECHNIPAMED-PLUS" IDNO 1003600077617

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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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

Boditech Med Inc. 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:	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:	Eyul Choi **Dr. Eui Yul Choi / CEO**

REPUBLICA MOLDOVA, mun. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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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 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

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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 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:	Eyulchoi **Dr. Eui Yul Choi / CEO**

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

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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:	Eyulchoi **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:	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

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

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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:	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:	Eyulchoi **Dr. Eui Yul Choi / CEO**

ECHIPAMED-PLUS SRL CHIŞINĂU, SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA IDNO 1003600077677

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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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

"ECHIPAMED-PLUS" IDNO 1003600077671

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

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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

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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 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:	Eyul choi Dr. Eui Yul Choi / CEO

REPUBLICA MOLDOVA mun. CHIŞINAU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHNOMED-PLUS" IDNO 1003600077617

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

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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

REPUBLICA MOLDOVA mun. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHIPAMED-PLUS" IDNO 1003600077677

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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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

Boditech Med Inc. 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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

RA-DOC-11945 (Rev. 01)

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 거두안1길 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 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

"CHIPAMED-PLUS" CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1003600076177 REPUBLICA MOLDOVA

Boditech Med Inc. 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 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:	Eyul Choi **Dr. Eui Yul Choi / CEO**

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

RA-DOC-III-66 (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 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:	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
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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 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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"CHIPAMED-PLUS"

RA-DOC-68 (Rev.07)

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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

REPUBLICA MOLDOVA mun. CHIŞINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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:

Eui Yul Choi

Dr. Eui Yul Choi / CEO

"ECHIPAMED-PLUS"

RA-DOC-0186 (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 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

"ECHIPAMED-PLUS" SRL CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA IDNO 1003200077677

RA-DOC-11-00 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:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

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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 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

"ECHIPAMED-PLUS" IDNO 1003600077677

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

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:

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
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