

# 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 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

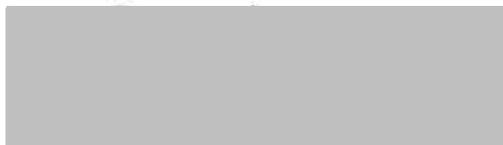
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Standards applied: ISO 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,  
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,  
EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,  
EN ISO 18113-2:2011

Place, Date of Issue:



Signature:



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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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,  
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,  
EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,  
EN ISO 18113-2:2011

Place, Date of Issue:



Signature:



## ATITIKTIES DEKLARACIJA

Gamintojas:	„Boditech Med Inc.“ 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korėjos Respublika
Atstovas Europoje:	„Obelis s.a.“ Bd. General Wahis, 53, 1030 Briuselis, Belgija
Gaminys:	„Boditech CRP Control“ kontrolė Kat. nr.: CFPO-100
Klasifikacija	Kita (MPD II priede nenurodyta; ne savityros priemonė)
Atitikties vertinimo eiga:	Savideklaracija pagal MPD III priedą

Šiuo dokumentu patvirtiname, kad pirmiau nurodyti gaminiai atitinka Tarybos Direktyvos 98/79/EB dėl *in vitro* diagnostikos medicinos priemonių nuostatas. Visus patvirtinančius dokumentus turi gamintojas ir tik gamintojas yra atsakingas už atitikties deklaraciją.

Taikomi standartai:	EN ISO 15223-1:2021, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019, EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011, EN ISO 18113-2:2011,
Išdavimo vieta ir data:	Chuncheon, Korėja, 2022 m. gegužės 20 d.

Parašas:



2024 m. lapkričio 6 d.

Aš, Natalija Tkačenko, vertimų biuro „INTERPRETUM“ vertėja, prisiimu atsakomybę už vertimo iš anglų kalbos į lietuvių kalbą teisingumą.

Vertimų biuras UAB "INTERPRETUM"  
Įmonės kodas 302299561  
Adresas: Donelaičio g. 33-114, Kaunas LT-44240, Lietuva  
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El.paštas: [interpretum@inbox.lt](mailto:interpretum@inbox.lt)



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European Representative: OBELIS S.A  
Bd. Général Wahis 53, 1030 Brussels, Belgium

Product: AFIAS MxA/CRP  
Cat. No. : SMFP-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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,  
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,  
EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,  
EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, March 20, 2022

Signature:



# 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 MxA/CRP Control  
Cat. No. : CFPO-382

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 15223-1:2021, EN ISO 13485:2016, EN 13612:2002,  
EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019,  
EN 13975:2003, EN ISO 17511:2021, EN ISO 18113-1:2011,  
EN ISO 18113-2:2011

Place, Date of Issue: Chuncheon, Korea, May 20, 2022

Signature:

