

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-1 Cat. No. : FPRR019
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
<p>We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic medical devices and the RoHS Directive 2011/65/EC of European Parliament and of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment. All supporting documentation is retained under the premises of the manufacturer.</p>	
Standards applied:	EN ISO 15223-1:2016, EN ISO 13485:2016, EN 13612:2002, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 61010-1:2010, EN 61010-2-101:2002, EN 55011:2009 / A1:2010 (CISPR 11:2009 / A1:2010), EN 61326-1:2013, EN 61326-2-6:2006, EN 62304:2006, EN 61000-3-2:2014, EN 61000-3-3:2013

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-I-10 (Rev. 05)

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Boditech Med Inc.'s AFIAS-1 fulfill according to IEC 62321:2008, procedure for six regulated substances in electro technical products.

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls, PBBs
- Polybrominated Diphenyl Ethers, PBDEs

Test report No.

T2016-09095

Date of Test

2016. 09. 02 ~ 2016. 10. 05

Verification of conformity by

KTC (Korea Testing Certification)

[15809] 74, LS-ro 115beon-gil, Gunpo-si, Gyeonggi-do,
Republic of Korea

Place, Date of Issue:

Chuncheon, Korea, March 29, 2019

Signature:



Dr. Eui Yul Choi / CEO