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-6 Cat. No. : FPRR020
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 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.

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
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DECLARATION OF CONFORMITY

Boditech Med Inc.'s AFIAS-6 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.	T2016-09094
Date of Test	2016. 09. 02 ~ 2016. 10. 17
Verification of conformity by	KTC (Korea Testing Certification) [15809] 74, LS-ro 115beon-gil, Gunpo-si, Gyonggi-do, Republic of Korea
Place, Date of Issue:	Chuncheon, Korea, March 29, 2019
Signature:	Eyul Choi **Dr. Eui Yul Choi / CEO**

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