

EU DECLARATION OF CONFORMITY

Manufacturer:	Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea (SRN: KR-MF-000011028)
European Representative:	Obelis s.a. Bd. Général Wahis, 53, 1030 Brussels, Belgium (SRN: BE-AR-000000106)
Product:	AFIAS-1 - Catalog No.: FPRR019 - Basic UDI-DI: 880613301005BL
Intended use:	AFIAS-1 is an analyzer intended for use in conjunction with fluorescence immunoassay (FIA) kits for quantitative, semi-quantitative and qualitative measurements of various analytes. For <i>in vitro</i> diagnostic use only.
Classification:	Class A (Rule 5) - According to the Annex VIII of the REGULATION (EU) 2017/746
Conformity Assessment Route:	According to the Annex II and Annex III of the REGULATION (EU) 2017/746

We, Boditech Med Inc., herewith declare under our sole responsibility that the above-mentioned product is in conformity with the following European Union harmonisation legislation.

- REGULATION (EU) 2017/746 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE 2011/65/EU OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 June 2011 on the 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 13485:2016, EN 13612:2002, EN ISO 14971:2019,
EN ISO 15223-1:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011,
EN 61010-1:2010, EN 61010-2-101:2017, EN IEC 61326-1:2021,
EN IEC 61326-2-6:2021, EN 62304:2006, EN 62366-1:2015,
ISO/TR 20416:2020, IEC 62321-5:2013, IEC 62321-7-1:2015,
IEC 62321-7-2:2017, IEC 62321-4:2013+AMD1:2017 CSV,
IEC 62321-6:2015, IEC 62321-8:2017

Place, Date of Issue: Chuncheon, Republic of Korea, April 23, 2023

Signature:


Eui Yul Choi / CEO

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