

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-10**

Basic UDI-DI	880613301031BM
Reference number (Catalog number)	FPRR038

Intended purpose: AFIAS-10 is an analyzer intended for use in conjunction with fluorescence immunoassay (FIA) kits for quantitative, semi-quantitative and qualitative measurements of various analytes.
For *in vitro* 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
- COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

All supporting documentation is retained under the premises of the manufacturer.

Standards applied: EN ISO 13485:2016, EN ISO 14971:2019, EN 13612:2002,
EN ISO 20417:2021, EN ISO 15223-1:2021, ISO 18113-1:2022,
ISO 18113-3:2022, ISO/TR 20416:2020, EN IEC 61326-1:2021,
EN IEC 61326-2-6:2021, EN 61010-1:2010/A1:2019,
EN IEC 61010-2-101:2022, EN 62366-1:2015, EN 62304:2006,
EN 62321-4:2014/A1:2017, EN 62321-5:2014, EN 62321-6:2015,
EN 62321-7-1:2015, EN 62321-7-2:2017, EN 62321-8:2017

Boditech Med Inc. www.boditech.co.kr

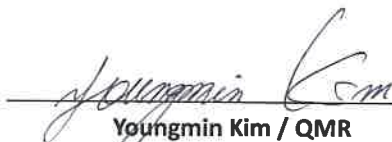
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won State 24398, KOREA
바디텍메드(주) 강원특별자치도 춘천시 동내면 거두단지 1길 43 (24398) Tel +82-33-243-1400 Fax +82-33-243-9373

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Place, Date of Issue:

Republic of Korea, March 22, 2024

Signature:


Youngmin Kim / QMR