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-3** - Catalog No.: FPRR040 - Basic UDI-DI: 880613301034BT
Intended use:	AFIAS-3 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 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, EN 62321-1:2013
Place, Date of Issue:	Chuncheon, Republic of Korea, February 27, 2023
Signature:	Eui Yul Choi **Eui Yul Choi / CEO**