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:	ichroma™ M2 Cat. No. : FPRR031
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 product meets 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 61010-2-101:2015, EN 61326-2-6:2013, EN 62304:2006
Place, Date of Issue:	Chuncheon, Korea, May 22, 2019
Signature:	Eui Yul Choi **Dr. Eui Yul Choi / CEO**

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