

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™ M3
Cat. No. : FPRR035

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 61010-2-101:2017, EN 61326-2-6:2013, IEC 60825-1:2014, EN 62304:2006

Place, Date of Issue: Chuncheon, Korea, February 26, 2020

Signature:



Dr. Eui Yul Choi / CEO

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