# DECLARATION OF CONFORMITY

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| Manufacturer: | Boditech Med Incorporated<br>43, Geodudanji 1-gil, Dongnae-myeon,<br>Chuncheon-si, Gang-won-do, 24398<br>REPUBLIC OF KOREA |
| European Representative: | OBELIS S.A<br>Bd. Général Wahis 53,<br>1030 Brussels,<br>Belgium |
| Product: | ichroma™ II<br>Cat. No. : FPRR021 |
| 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 products meet 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 and the manufacturer is exclusively responsible for the declaration of conformity..

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| 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 61010-2-101:2002, EN 55011:2009 / A1:2010 (CISPR 11:2009 / A1:2010), EN 61326-1:2013, EN 61326-2-6:2006, EN 62304:2006, EN 61000-3-2:2006/A1:2009/A2:2009, EN 61000-3-3:2013 |

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Boditech Med Inc.'s ichroma™ Reader fulfill according to IEC 62321:2008, procedure for six regulated substances in electro technical products.

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls, PBBs
- Polybrominated Diphenyl Ethers, PBDEs

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| Test report No. | T2016-09093 |
| Date of Test | 2016. 09. 02 ~ 2016. 11. 02 |
| Verification of conformity by | KTC (Korea Testing Certification)<br>[15809] 74, LS-ro 115beon-gil, Gunpo-si, Gyonggi-do, Republic of Korea |
| Place, Date of Issue: | Chuncheon, Korea, March 11, 2020 |

Signature:

Eui Yul Choi

**Dr. Eui Yul Choi / CEO**

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