# 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: | AFIAS COVID-19 Ab<br>Cat. No. : SMFP-72 |
| 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. 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 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN 13975:2003, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011 |
| Place, Date of Issue: | Chuncheon, Korea, March 24, 2020 |
| Signature: | Eui Yul Choi<br>**Dr. Eui Yul Choi / CEO** |

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