# Declaration of Conformity

| We declare, under our sole responsibility, that the product listed below conforms to the provisions of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. | |
|---|---|
| Manufacturer's name | Disior Oy |
| Manufacturer's address | Maria 01, Building 2, Lapinlahdenkatu 16, 00180 Helsinki, Finland |
| Device name | Bonelogic CMF Orbital |
| Classification | Class I (Annex IX Rule 12) |
| Conformity assessment route | Annex VII |
| GMDN Code (if applicable) | 46470 |
| Standards applied | ISO 14971:2007 Medical devices – Application of risk management to medical devices.<br>IEC 62304:2006 – Medical device software – Software life cycle processes.<br>IEC 62366-1:2015 Medical devices. Part 1: Application of usability engineering to medical devices. |

Authorized Signatory:

DocuSigned by:
Anna-Maria Henell
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| Anna-Maria Henell, CEO<br>26.11.2020 \| 17:40 EET | 26 November 2020<br>Date | Helsinki, Finland<br>Place of Issue |
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