




Declaration of Conformity		
Document # RND ORB DCO 001	Version 1.0	

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	<p>ISO 14971:2007 Medical devices – Application of risk management to medical devices.</p> <p>IEC 62304:2006 – Medical device software – Software life cycle processes.</p> <p>IEC 62366-1:2015 Medical devices. Part 1: Application of usability engineering to medical devices.</p>

Authorized Signatory:

<small>DocuSigned by:</small>  <small>9C8ED36D49A459</small> Anna-Maria Henell, CEO 26.11.2020 17:40 EET	26 November 2020 Date	Helsinki, Finland Place of Issue
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Change history

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0.1	Draft	17.12.2018	Markku Laitinen	Initial draft.
1.0	Signed	26.11.2020	Anna-Maria Henell	Approved, signed (ENG).

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