DISIOR

Declaration of Conformity

Manufacturer:	Disior Oy Maria 01, Building 2 Lapinlahdenkatu 16 00180 Helsinki, FINLAND
We declare that the product:	Software tool for orthopaedic anatomy characterization, model Bonelogic 2 conforms to the following European Union Directives and the standards identified in this declaration.
Technical file:	Issued for Software tool for orthopaedic anatomy characterization, model Bonelogic 2
EU Directive:	93/42/EEC Medical devices amended by Directive 2007/47/EC.
EC Product Classification:	Class II b (Annex IX Rule 10)
Conformity assessment route:	Annex II (excluding section 4)
Notified Body:	SGS Fimko, Notified Body 0598
EC Certificate:	Full Quality Assurance System FI20/871787
Standards:	EN ISO 13485:2016/AC:2018 Medical devices. Quality management systems. Requirements for regulatory purposes EN ISO 14971:2019 Medical devices. Application of risk management to medical devices (ISO 14971:2019) EN ISO 14155:2011 Clinical investigation of medical devices for human subjects. Good clinical practice (ISO 14155:2011) EN 62304:2006/A1:2015 Medical device software. Software life-cycle processes EN 62366-1:2015/AC:2016 Medical devices – Part 1: Application of usability engineering to medical devices

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Authorized Signatory:

DocuSigned by:
Sakari Soini
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Date	Place of Issue

Sakari Soini, CTO