EC Declaration of Conformity

Boule Medical AB declare that the product below:

Type of product; Cell counter

Article No	Brand name or trademark
1620040	Swelab Lumi

Is in conformity with the following regulations and directives and with harmonized standards:

Regulations/Directives	Standards
98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
2014/30/EU Electro Magnetic Compatibility Directive (EMC)	EN IEC 61326-1:2021 EN IEC 61326-2-6:2021
2014/35/EU Low Voltage Directive (LVD)	EN 61010-1:2010+A1:2019 EN 61010-2-101:2017 EN IEC 61010-2-081:2020
2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)	EN IEC 63000:2019

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Place and date of issue

Jesper Söderqvist, CEO

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