

EC Declaration of Conformity

Boule Medical AB declare that the product below:

Type of product; Cell counter

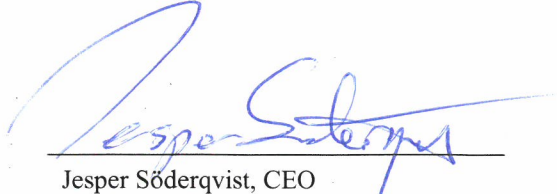
Article No	Brand name or trademark
1620040	Swelab Lumi

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

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

Stockholm 2022-05-25

Place and date of issue



Jesper Söderqvist, CEO

