

EU Declaration of Conformity

Boule Medical AB declare that the product below

Type of product; Cell counter

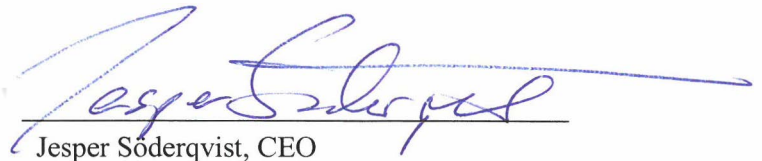
Article No	Brand name or trademark
1440101	H50V Veterinary Hematology System

is in conformity with the following directives and with harmonized and other relevant standards:

Directives	Standards
<i>2006/42/EC Machine Directive</i>	Fulfills standards for human use EN ISO 14971:2020
<i>2014/30/EU Electro Magnetic Compatibility Directive (EMC)</i>	EN IEC 61326-1:2021 EN IEC 61326-2-6:2021 EN 55011:2016/A1:2017/A11:2020/A2:2021, Class B CISPR 11:2015/AMD1:2016/AMD2:2019 EN IEC 61000-3-2:2019+A1:2021 EN IEC 61000-3-3:2013+A1:2019+A2:2021
<i>2014/35/EU Low Voltage Directive (LVD)</i>	EN IEC 61010-2-101:2017 EN IEC 61010-1:2010+A1:2019 EN 60825-1:2014/A11:2021
<i>2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)</i>	EN IEC 63000:2019
<i>2014/53/EU Radio Equipment Directive (RED)</i>	ETSI EN 301 489-1 V2.2.3 (2019-11) ETSI EN 301 489-3 V2.3.2 (2023-01) ETSI EN 300 330 V2.1.1 (2017-02)

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Place and date of issue



Jesper Söderqvist, CEO

