

CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Cell counter

Article No	Brand name or trademark
1420001	Exigo H400

are in conformity with the following directives and with harmonized 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 61326-2-6:2021 EN55011:2016/A1:2017/A11:2020/A2:2021,ClassB EN 61000-4-2:2009, EN 61000-4-3:2020, EN 61000-4-4:2012, EN 61000-4-5:2014/A1:2017, EN 61000-4-6:2014, EN 61000-4-8:2010, EN 61000-4-11:2020
<i>2014/35/EU Low Voltage Directive (LVD)</i>	EN 61010-1:2001 IEC 61010-2-081:2001 + A1:2003 CAN/CSA-C22.2 No 61010-1: 2004 UL 61010-1: 2004
<i>2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)</i>	EN IEC 63000:2019

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Place and date of issue


Jesper Söderqvist, CEO