

EC Declaration of Conformity

Boule Medical AB declare that the products below

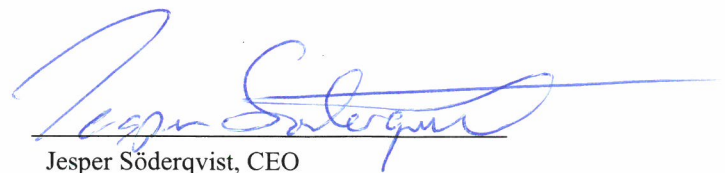
Type of product; Cell counter

Article No	Brand name or trademark
1600001	Quintus 5-part analyzer

are 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 61326-1:2006, EN 61326-2-6:2006 IEC 61326-2-6:2020 EN 55011:2009/A1:2010 class B EN 61000-3-2:2006/A1:2009/A2:2009 EN 61000-3-3:2008 EN 61000-4-2:2009 EN 61000-4-3:2006/A1:2008 EN 61000-4-4:2004/A1:2010 EN 61000-4-5:2006 EN 61000-4-6:2009 EN 61000-4-8:2010 EN 61000-4-11:2004
<i>2014/35/EU Low Voltage Directive (LVD)</i>	EN 61010-1: 2001 EN 61010-2-101:2002 UL 61010-1, 2012 CAN/CSA-C22.2 No 61010-1, 2012 IEC 61010-2-101: 2002
<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

