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

BL10728-1
Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
E-mail: info@boule.com
www.boule.com