

## *CE Declaration of Conformity*

Boule Medical AB declare that the products below

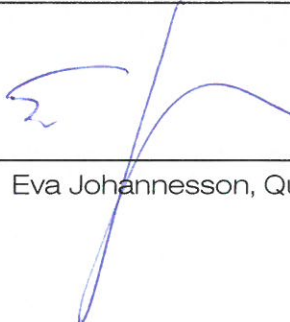
Type of product; Cellcounter

Article No	Brand name or trade mark
1420021	Medonic M-series M32B
1420022	Medonic M-series M32M
1420023	Medonic M-series M32C
1420024	Medonic M-series M32C AR
1420025	Medonic M-series M32S BD
1420026	Medonic M-series M32S BD AR
1420027	Medonic M-series M32S SA
1420028	Medonic M-series M32S SA AR

are in conformity with the following directives and with harmonized standards:

Directives	Standards
<i>98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>2004/108/EEC Electro Magnetic Compatibility Directive (EMC) with amendment 92/31/EEC</i>	Emission EN 61326-1:2013, SS-EN55011:2009, +A1:2010, Class B EN 61326-2-6:2013  Immunity: EN 61326-1:2013 EN 61326-2-6:2013 EN 61000-4-2, -3, -4, -5, -6, -11
<i>2006/95/EEC Low Voltage Directive (LVD)</i>	IEC 61010-1: 2001 IEC 61010-2-081:2001 + A1:2003 IEC 61010-2-101:2002 CAN/CSA-C22.2 No 61010-1:2004 UL 61010-1:2004
<i>2012/19/EU Waste of electrical and electronic equipment (WEEE)</i>	--

Stockholm 2016-09-05  
Date and place of issue

  
 Eva Johannesson, Quality Assurance

