

CE Declaration of Conformity

Boule Medical AB declare that the products below

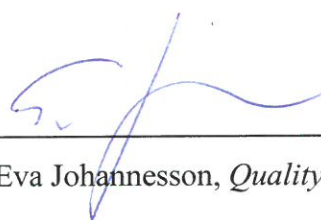
Type of product;	Cellcounter	S/N
Brand name or trade mark;	Medonic M-series	M16/M20
	Medonic M-series	M16M/M20M
	Medonic M-series	M16C/M20C
	Medonic M-series	M16S/M20S

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

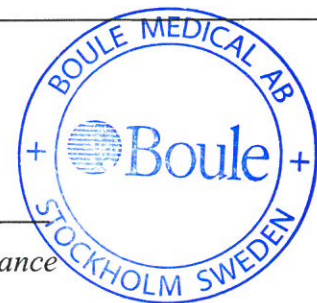
Regulations/Directives	Standards
98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
2014/30/EU Electro Magnetic Compatibility Directive (EMC)	Emission: EN 61326-1:2006, SS-EN55011:2009, +A1:2010, Class B, EN 61000-3-2:2006 Immunity: EN 61326-1:2006, +A1 and A2 2009, EN 61000-4-2, -3, -4, -5, -6, -11
2014/35/EU Low Voltage Directive (LVD)	IEC 61010-1: 2001 IEC 61010-2-081:2001 + A1 IEC 61010-2-101:2002 CAN/CSA-C22.2 No 61010-1: second edition UL 61010-1: second edition
2012/19/EU Waste of electrical and electronic equipment (WEEE)	--
2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)	--

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Date and place of issue



Eva Johannesson, *Quality Assurance*



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