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)	--

BOULE MEDICAL AB Boule STOCKHOLM SWEDEN

Stockholm 2016-11-25

Date and place of issue

Eva Johannesson, *Quality Assurance*

1504136

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

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