CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Cellcounter

Article No	Brand name or trade mark
1400002	Medonic M-series M16
1400062	Medonic M-series M20
1400005	Medonic M-series M16C
1400006	Medonic M-series M20C
1400007	Medonic M-series M16C+ABR
1400008	Medonic M-series M20C+ABR
1400003	Medonic M-series M16M-GP
1400004	Medonic M-series M20M-GP
1400009	M-series M16S BD
1400010	M-series M20S BD

Article No	Brand name or trade mark
1400011	M-series M16S BD ABR
1400012	M-series M20S BD ABR
1400065	Medonic M-series M16S Sarstedt
1400066	Medonic M-series M20S Sarstedt
1400067	M-series M16S Sarstedt ABR
1400068	M-series M20S Sarstedt ABR
1400074	M-series M16C US
1400073	M-series M16M US
1400075	M-series M16S BD ABR US

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

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