

CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Cellcounter

Article No	Brand name or trade mark	Article No	Brand name or trade mark
1400002	Medonic M-series M16	1400011	M-series M16S BD ABR
1400062	Medonic M-series M20	1400012	M-series M20S BD ABR
1400005	Medonic M-series M16C	1400065	Medonic M-series M16S Sarstedt
1400006	Medonic M-series M20C	1400066	Medonic M-series M20S Sarstedt
1400007	Medonic M-series M16C+ABR	1400067	M-series M16S Sarstedt ABR
1400008	Medonic M-series M20C+ABR	1400068	M-series M20S Sarstedt ABR
1400003	Medonic M-series M16M-GP	1400074	M-series M16C US
1400004	Medonic M-series M20M-GP	1400073	M-series M16M US
1400009	M-series M16S BD	1400075	M-series M16S BD ABR US
1400010	M-series M20S BD		

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 61326-1:2006, 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
<i>2006/95/EEC Low Voltage Directive (LVD)</i>	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
<i>2012/19/EU Waste of electrical and electronic equipment (WEEE)</i>	--

Stockholm 2014-08-28
Date and place of issue


 Debora Thernström, Quality Assurance
