

CE Declaration of Conformity

Boule Medical AB declare that the products below

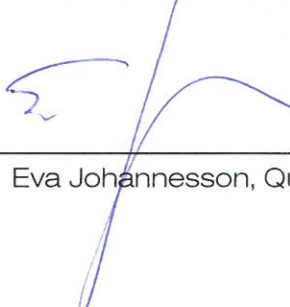
Type of product; Cellcounter

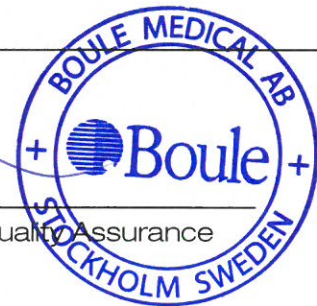
Article No	Brand name or trade mark
1420021	Medonic M-series M32B
1420022	Medonic M-series M32M
1420023	Medonic M-series M32C
1420024	Medonic M-series M32C AR
1420025	Medonic M-series M32S BD
1420026	Medonic M-series M32S BD AR
1420027	Medonic M-series M32S SA
1420028	Medonic M-series M32S SA AR

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



CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; **Cellcounter**


Article No	Brand name or trade mark
1600001	Quintus 5-part analyzer
1091348	Quintus autoloader

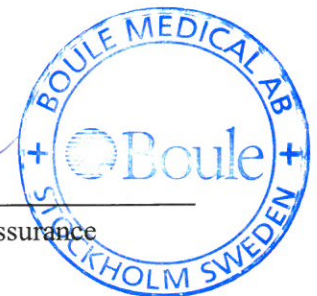
are in conformity with the following regulations and directives and with harmonized standards:

Regulations/Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>2014/30/EU Electro Magnetic Compatibility Directive (EMC)</i>	EN 61326-1:2006, EN 61326-2-6:2006 SS-EN55011:2009 +A1 EN 61000-3-2:2006 + A1 + A2 EN 61000-3-3:2008 EN 61000-4-2:2009 EN 61000-4-3:2006 + A1 EN 61000-4-4:2004 + A1 EN 61000-4-5:2006 EN 61000-4-6:2009 EN 61000-4-8:2010 EN 61000-4-11:2004
<i>2014/35/EU Low Voltage Directive (LVD)</i>	EN 61010-1: 2001 EN 61010-2-101:2002
<i>2012/19/EU Waste of electrical and electronic equipment (WEEE)</i>	--
<i>2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)</i>	--

Stockholm 2016-11-25

Date and place of issue


 Eva Johannesson, Quality Assurance



CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Hematology reagents

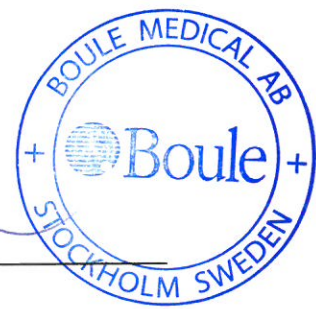
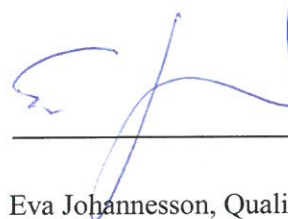
Article No	Brand name or trade mark
1504122	Medonic M-series Diluent, 20L
1504123	Medonic M-series Lyse 5L
1504128	Medonic M-series DualPack

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

Regulations/Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)</i>	
<i>1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)</i>	

Stockholm 2016-11-25

Date and place of issue



Eva Johannesson, Quality Assurance



CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; *Hematology calibrator/control*

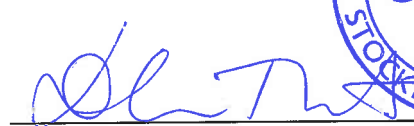
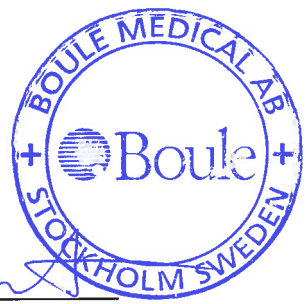
Article No	Brand name or trade mark
1504025	Boule Cal 1x3.0 ml
1504045	Boule Cal 2x3.0 ml
1504041	Boule Con-Diff Low 4.5 ml
1504020	Boule Con-Diff L 1x4.5 ml
1504176	Boule Con-Diff L 6x4.5 ml
1504040	Boule Control Normal 4.5 ml
1504019	Boule Con-Diff N 1x4.5 ml
1504043	Boule Con-Diff N 6x4.5 ml
1504042	Boule Control High 4.5 ml
1504021	Boule Con-Diff H 1x4.5 ml
1504216	Boule Con-Diff H 6x4.5 ml
1504022	Boule Con-Diff Tri-L 6x4.5 ml
1504289	Boule Con-Diff L 25x3.0 ml
1504288	Boule Con-Diff N 25x3.0 ml
1504290	Boule Con-Diff H 25x3.0 ml

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

Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure

Stockholm 2014-08-28

Date and place of issue

Debora Thernström, *Quality Assurancer*

CE Declaration of Conformity

Boule Medical AB declare that the product(s) below

Type of product; Cleaning solutions

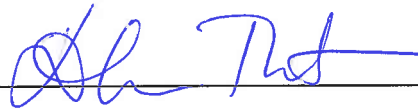
Article No	Brand name or trade mark
1504111	Boule Cleaning Kit, 3 x 450 ml

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

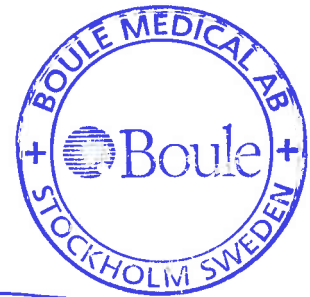
Directives	Standards
98/79/EC <i>In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure

Stockholm 2014-08-28

Date and place of issue



Debora Thernström, Quality Assurance



CE Declaration of Conformity

Boule Medical AB declare that the product(s) below

Type of product; Cleaning solutions

Article No	Brand name or trade mark
1504112	Boule Enzymatic Cleaner, 100 ml

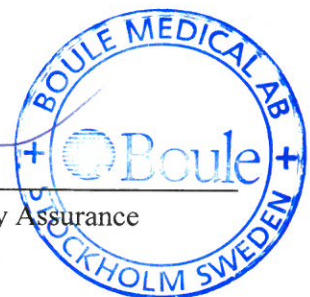
are in conformity with the following regulations and directives and with harmonized standards:

Regulations/Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),</i>	
<i>1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)</i>	

Stockholm 2016-11-25

Date and place of issue


Eva Johannesson, Quality Assurance



EC Declaration of Conformity

Boule Medical AB declare that the product(s) below

Type of product; **Cleaning solutions, Hematology analyzer**

Article No	Brand name or trade mark
1504113	Boule Hypochlorite 2% Cleaner, 500 ml

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

Directives	Standards
<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure

Stockholm 2014-08-28
Date and place of issue




Debora Thernström, Quality Assurance

CE Declaration of Conformity

Boule Medical AB declare that the product below

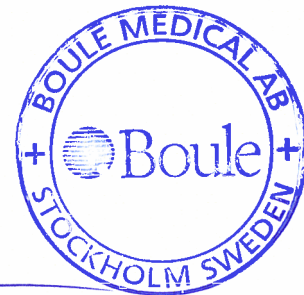
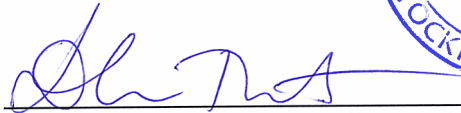
Type of product; Blood collecting tube (micro capillary)

Article No	Brand name or trade mark
1070039	Boule MPA Micro Pipettes Plastic, EDTA, 1 x 100 pcs
1070030	Boule MPA Micro Pipettes Plastic, EDTA, 10x100 pcs

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

Directives	Standards
98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure

Stockholm 2014-08-28



Date and place of issue

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CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; Hematology reagents

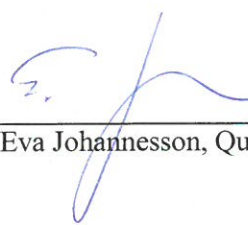
Article No	Brand name or trade mark
1504291	Quintus 5-Part Diluent, 20L
1504292	Quintus 5-Part Lyse, 5L
1504293	Quintus 5-Part Stopper, 5L
1504373	Quintus 5-Part Stopper, 1L

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

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<i>98/79/EC In Vitro Diagnostic Medical Device Directive (IVD)</i>	Using Annex III as the conformity assessment procedure
<i>1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),</i>	
<i>1272/2008/EC classification, labelling and packaging of substances and mixtures (CLP)</i>	

Stockholm
Date and place of issue

2016-11-25


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CE Declaration of Conformity

Boule Medical AB declare that the products below

Type of product; *Hematology calibrator/control*

Article No	Brand name or trade mark
1504309	Boule Cal-5Diff 1x3.0 ml
1504316	Boule Con-5Diff L 1 x3.0 ml
1504313	Boule Con-5Diff L 6 x3.0 ml
1504315	Boule Con-5Diff N 1 x3.0 ml
1504312	Boule Con-5Diff N 6 x3.0 ml
1504314	Boule Con-5Diff H 1x x3.0 ml
1504311	Boule Con-5Diff H 6x x3.0 ml
1504310	Boule Con-5Diff Tri-Level 3 x 2 x3.0 ml

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Article No	Brand name or trade mark
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Debora Thernström, Quality Assurance