

To whom it may concern

Radiometer Medical ApS  
Åkandevej 21  
2700 Brønshøj  
Denmark  
Phone: +45 38 27 38 27  
Fax: +45 38 27 27 27  
CVR No. 27 50 91 85  
[www.radiometer.com](http://www.radiometer.com)

April 15, 2010

### AUTHORIZATION

Hereby we, company Radiometer Medical ApS, Aakandevej 21, DK-2700 Bronshøj, Denmark, authorize Echipamed Plus, Valea Trandafirilor str. 24B, off. 80, MD-2001 Chisinau, Moldova, to be our official and exclusive distributor on the territory of Moldova, at its own expense and peril to participate in negotiations, tenders, to sign contracts and to execute any other actions necessary for sale and marketing of our products in Moldova.

This authorization is valid till revoked.

Kind regards  
Radiometer Medical ApS



## EU Declaration of Conformity

<b>Radiometer Medical ApS</b> Åkandevvej 21 2700 Brønshøj Denmark	<b>SRN:</b> DK-MF-000016271
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We, Radiometer Medical ApS, declare with the issue of this DoC, that we as manufacturer take the sole responsibility for the products mentioned below.

We, Radiometer Medical ApS, declare that the below mentioned product(s) meet(s) the applicable requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic Medical Devices, as specified in annex IV.

### RISK Classification in accordance with Annex VIII:

☒ Class A

**Product family:** ABL8xx Product line

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
S8375 Cleaning Solution with additive	944-126	57006900046MZ	W0201040185	59058
<b>Intended purpose</b>				
For cleaning the measuring system of the ABL800 analyzers.				
Name	Ref No.	Basic UDI-DI	EMDN	GMDN
S4980 Rinse Solution	944-130	57006900044MV	W0201040185	59058
S4980 Rinse Solution	944-131	57006900044MV	W0201040185	59058
S4980 Rinse Solution	944-132	57006900044MV	W0201040185	59058
<b>Intended purpose</b>				
For automatic rinse of the measuring system in the ABL800 analyzers.				
Name	Ref No.	Basic UDI-DI	EMDN	GMDN
S4987 Rinse Solution II	944-155	57006900045MX	W0201040185	59058




S4987 Rinse Solution II	944-158	57006900045MX	W0201040185	59058
S4987 Rinse Solution II	944-159	57006900045MX	W0201040185	59058
<b>Intended purpose</b>				
For automatic rinse of the measuring system in the ABL837/827/817 analyzers.				
<b>Name</b>	<b>Ref No.</b>	<b>Basic UDI-DI</b>	<b>EMDN</b>	<b>GMDN</b>
Disposable waste container	905-802	57006900088NH	W0201040185	62172
<b>Intended purpose</b>				
For collection and disposal of blood waste and used solutions from the analyzer.				

**Common Specification:**

Currently non-applicable

**Date of the first issuance of the EU Declaration of Conformity:** 2022-May-06

**Issuance:**

	Copenhagen, Denmark	06 May 2022
Signature	Issued in	Date
Casper Folsing	Director, Regulatory Affairs	
Name	Position	



## EC Declaration of Conformity

### Radiometer Medical ApS

Åkandevvej 21

DK-2700 Brønshøj

Denmark

We hereby declare that the product(s) described below meets the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998, on *in vitro* diagnostic medical devices (IVDD) as specified in Annex III.

**Class:** ☒ General ☐ Annex II/List A ☐ Annex II/List B

**Product family:** Gas – Gas Mixture

Name	Ref. No.	GMDN	CE-mark
Carbon dioxide, 100 % CO <sub>2</sub>	962-045	52859	2003-12
Gas 1 – Gas Mixture – N <sub>2</sub> CO <sub>2</sub> O <sub>2</sub>	962-140	52859	2003-12
Gas 2 – Gas Mixture – N <sub>2</sub> CO <sub>2</sub>	962-141	52859	2003-12
Calibration Gas Mixture for Blood Gas Analyzers – Gas 1	962-169	52859	2003-12
Calibration Gas Mixture for Blood Gas Analyzers – Gas 2	962-170	52859	2003-12

#### Issuance:

Name: Mette Luxhøj

Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature: 

Date: 2020-10-22



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### RISK Classification in accordance with Annex VIII:

☒ Class A

**Product family:** ABL accessories

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
Hypochlorite Solution (S5362)	943-906	57006900090N4	W0201040185	59058
<b>Intended purpose</b>				
Intended for protein removal and decontamination of ABL analyzers.				

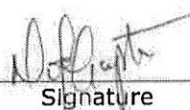


**Common Specification:**

*Currently non-applicable*

**Date of the first issuance of the EU Declaration of Conformity:** 2022-11-23

**Issuance:**

 <hr/> Signature	Copenhagen, Denmark <hr/> Issued in	2022-11-23 <hr/> Date
Noopur Gupta <hr/> Name	Director, Regulatory Affairs <hr/> Position	

# EC Declaration of Conformity

## Radiometer Medical ApS

Åkandevvej 21

DK-2700 Brønshøj

Denmark

We hereby declare that the product(s) described below meets the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998, on *in vitro* diagnostic medical devices (IVDD) as specified in Annex III.

**Class:**

☒ General

☐ Annex II/List A

☐ Annex II/List B

**Product family:** Membrane box

Name	Ref. No.	GMDN	CE-mark
D711 Membrane box for E1001 electrode – Ref	942-058	59241	2003-12
D722 Membrane box for E722 electrode – K <sup>+</sup>	942-059	52892	2003-12
D733 Membrane box for E733 electrode – Ca <sup>2+</sup>	942-060	52874	2003-11
D744 Membrane box for E744 electrode – Cl <sup>-</sup>	942-061	52876	2003-12
D755 Membrane box for E755 electrode – Na <sup>+</sup>	942-062	52896	2004-02
D788 Membrane box for E788 electrode – pCO <sub>2</sub>	942-063	54500	2003-12
D799 Membrane box for E799 electrode – pO <sub>2</sub>	942-064	54501	2003-12
D7066 Membrane box for E7066 electrode – Glucose	942-065	53303	2003-11
D7077 Membrane box for E7077 electrode – Lactate	942-066	30208	2003-11
D8088/D8089 CREA A and CREA B membranes	942-073	53252	2006-11



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**Class:**

☒ General

☐ Annex II/List A

☐ Annex II/List B

#### Product family: ABL800 FLEX – Solutions and Accessories

Name	Ref. No.	GMDN	CE-mark
S1820 Calibration solution 1	944-127	35933	2004-12
S1820 Calibration solution 1	944-128	35933	2004-12
S1830 Calibration solution 2	944-129	35933	2004-12
S1827 Calibration Solution 1	944-133	35933	2006-11
S1837 Calibration Solution 2	944-134	35933	2006-11
S1827 Calibration Solution 1	944-135	35933	2006-11
S8377 Cleaning Met II Solution	944-136	59058	2006-11

#### Issuance:

Name: Casper Folsing

Place: Copenhagen, Denmark

Title: Director Regulatory Affairs

Signature:



Date:

25-May-2022





# EC Declaration of Conformity

## Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj

Denmark

We hereby declare that the product(s) described below meets the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998, on *in vitro* diagnostic medical devices (IVDD) as specified in Annex III.

**Class:** ☒ General ☐ Annex II/List A ☐ Annex II/List B

**Product family:** AutoCheck

Name	Ref. No.	GMDN	CE-mark
S7335 AutoCheck3+ LEVEL 1	944-082	52860	2003-12
S7345 AutoCheck3+ LEVEL 2	944-083	52860	2004-02
S7355 AutoCheck3+ LEVEL 3	944-084	52860	2004-02
S7365 AutoCheck3+ LEVEL 4	944-085	52860	2003-12
S7735 AutoCheck5+ LEVEL 1	944-074	52860	2003-12
S7745 AutoCheck5+ LEVEL 2	944-075	52860	2003-12
S7755 AutoCheck5+ LEVEL 3	944-076	52860	2003-12
S7765 AutoCheck5+ LEVEL 4	944-077	52860	2003-12
S7835 AutoCheck6+ LEVEL 1	944-094	52860	2006-11
S7845 AutoCheck6+ LEVEL 2	944-095	52860	2006-11
S7855 AutoCheck6+ LEVEL 3	944-096	52860	2006-11
S7865 AutoCheck6+ LEVEL 4	944-097	52860	2006-11




**Issuance:**

Name: Gitte Juel Friis

Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature: 

Date: 2019-10-15

# EC Declaration of Conformity

## Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj

Denmark

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**Class:** ☒ General ☐ Annex II/List A ☐ Annex II/List B

**Product family:** ABL series – Solutions and Accessories

Name	Ref. No.	GMDN	CE-mark
Clot Catcher	906-016	66079	2003-10
ABL700 Series and ABL800 FLEX Clot Catcher	906-020	66079	2003-11
S5362 Hypochlorite Solution	943-906	59058	2003-12
S7770 ctHb Calibration Solution	944-021	35933	2003-12

### Issuance:

Name: Henriette Christiansen

Place: Copenhagen, Denmark

Title: Director Regulatory Affairs

Signature: 

Date: 18 May 2022







By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Radiometer Medical ApS  
Åkandevej 21  
2700 Brønshøj  
Denmark

Holds Certificate Number:

**MD 782470**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture, installation and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, blood collection devices and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-02-16

Latest Revision Date: 2023-11-28

Effective Date: 2023-12-16

Expiry Date: 2026-12-15

Page: 1 of 2



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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 8460 780  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.





Certificate No: **MD 782470**

Location

Registered Activities

Radiometer Medical ApS  
Åkandevvej 21  
2700 Brønshøj  
Denmark

Design, development, manufacture, installation and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, blood collection devices and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

Radiometer Medical ApS  
Indian Development Center hosted by  
Beckman Coulter India Pvt. Ltd  
Building 6A, Unit 401 & 402 and 501 & 502  
RMZ Eco World  
Sarjapura Marathalli Outer Ring Road  
Bengaluru  
560103  
India

Design and development of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers and point of care systems.



Original Registration Date: 2023-02-16

Effective Date: 2023-12-16

Latest Revision Date: 2023-11-28

Expiry Date: 2026-12-15

Page: 2 of 2

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