Digitally signed by Iurchevici Valeriu
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Location: Moldova
MOLDOVA EUROPEANĂ

RADIOMETER

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

To whom it may concern

April 15, 2010

**AUTHORIZATION**

Hereby we, company Radiometer Medical ApS, Aakandevej 21, DK-2700 Bronshoj, 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

RADIOMETER MEDICAL ApS International Sales Division

Simon Kvetny
Director of Sales, CIS

REPUBLICA MOLDOVA mun. CHIŞINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

RADIOMETER

# EU Declaration of Conformity

| | |
|---|---|
| **Radiometer Medical ApS**<br>Åkandevej 21<br>2700 Brønshøj<br>Denmark | **SRN:** DK-MF-000016271 |

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 |
| **Intended purpose** | | | | |
| 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 |
| **Intended purpose** | | | | |
| 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 |
| **Intended purpose** | | | | |
| For automatic rinse of the measuring system in the ABL837/827/817 analyzers. | | | | |
| **Name** | **Ref No.** | **Basic UDI-DI** | **EMDN** | **GMDN** |
| Disposable waste container | 905-802 | 57006900088NH | W0201040185 | 62172 |
| **Intended purpose** | | | | |
| 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:**

Casper Folsing
Signature

Copenhagen, Denmark
Issued in

06 May 2022
Date

Casper Folsing
Name

Director, Regulatory Affairs
Position

RADIOMETER

# 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:** Gas – Gas Mixture

| Name | Ref. No. | GMDN | CE-mark |
|---|---|---|---|
| Carbon dioxide, 100 % $CO_2$ | 962-045 | 52859 | 2003-12 |
| Gas 1 – Gas Mixture – $N_2$ $CO_2$ $O_2$ | 962-140 | 52859 | 2003-12 |
| Gas 2 – Gas Mixture – $N_2$ $CO_2$ | 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

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" IDNO 1003600077677

RADIOMETER

# EU Declaration of Conformity

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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 |
| **Intended purpose** | | | | |
| 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:**

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

RADIOMETER

# 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:** 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 – $K^+$ | 942-059 | 52892 | 2003-12 |
| D733 Membrane box for E733 electrode – $Ca^{2+}$ | 942-060 | 52874 | 2003-11 |
| D744 Membrane box for E744 electrode – $Cl^-$ | 942-061 | 52876 | 2003-12 |
| D755 Membrane box for E755 electrode – $Na^+$ | 942-062 | 52896 | 2004-02 |
| D788 Membrane box for E788 electrode – $pCO_2$ | 942-063 | 54500 | 2003-12 |
| D799 Membrane box for E799 electrode – $pO_2$ | 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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# 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: 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: Casper Folsing Date: 25-May-2022

RADIOMETER

# 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: (Gitte Juel Fm)

Date: 2019-10-15

RADIOMETER

# 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:** ABL series – Solutions and Accessories

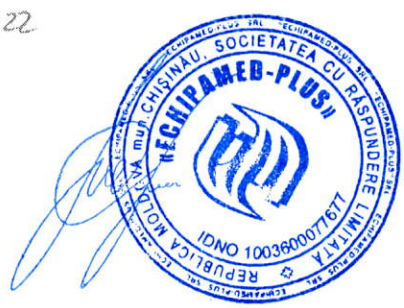
| Name | Ref. No. | GMDN | CE-mark |
|---|---|---|---|
| Clot Catcher | 906-016 | 66079 | 2003-10 |
| ABL700 Series and ABL800 FLEX Clot Catcher | 906-020 | 66079 | 2003-11 |
| S5362 Hypochlorite Solution | 943-906 | 59058 | 2003-12 |
| S7770 ctHb Calibration Solution | 944-021 | 35933 | 2003-12 |

**Issuance:**

Name: Henriette Christiansen Place: Copenhagen, Denmark

Title: Director Regulatory Affairs

Signature: Henriette Christiansen Date: 18 May 2022



bsi.

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



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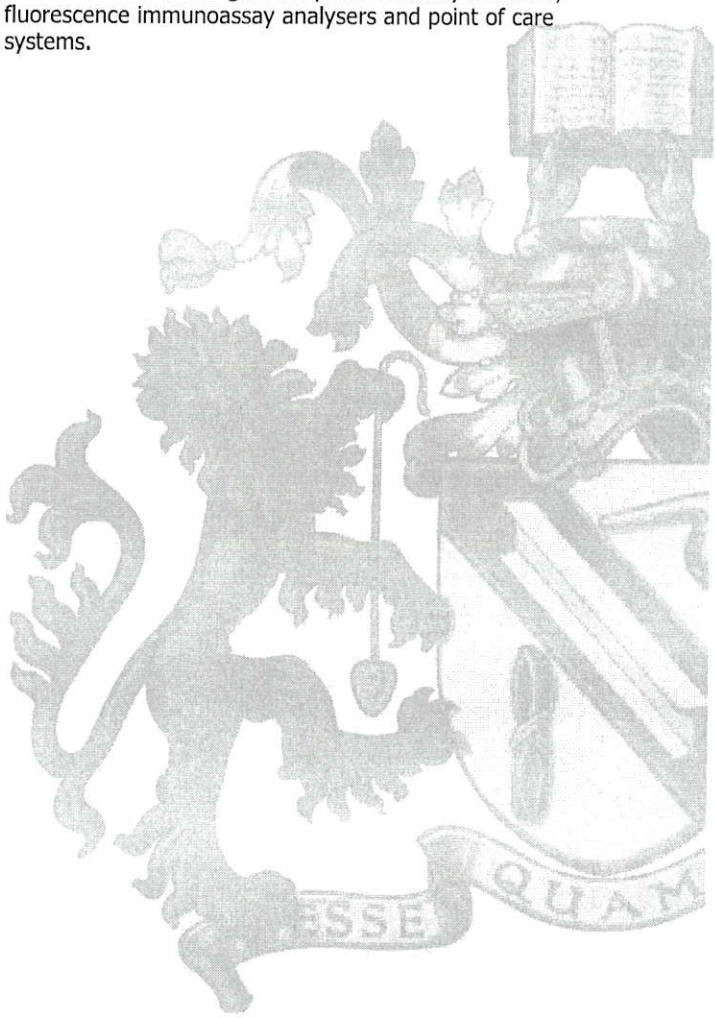
Certificate No: **MD 782470**

| Location | Registered Activities |
|---|---|
| Radiometer Medical ApS<br>Åkandevej 21<br>2700 Brønshøj<br>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<br>Indian Development Center hosted by<br>Beckman Coulter India Pvt. Ltd<br>Building 6A,Unit 401 & 402 and 501 & 502<br>RMZ Eco World<br>Sarjapura Marathalli Outer Ring Road<br>Bengaluru<br>560103<br>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
Latest Revision Date: 2023-11-28

Effective Date: 2023-12-16
Expiry Date: 2026-12-15