Digitally signed by Iurchevici Valeriu
Date: 2023.12.14 19:28:40 EET
Reason: MoldSign Signature
Location: Moldova

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

"ECHIPAMED-PLUS" IDNO 1003600077677

RADIOMETER

EU Declaration of Conformity

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj 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

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	**SRN:** DK-MF-000016271

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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 Issued in	2022-11-23 Date
Noopur Gupta Name	Director, Regulatory Affairs Position	

RADIOMETER

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: 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

Issuance:

Name: Henriette Christiansen Place: Copenhagen, Denmark

Title: Director Regulatory Affairs

Signature: Henriette Christiansen Date: 18 May 2022

1 Change History

Revision	Author	Change Description
01	ZAL	New form is implemented
02	ZAL	Item number: 942-045, 942-047, 942-048, 942-050 and 942-054 are discontinued
03	ZAL	Item number: 942-046 is discontinued
04	ZAL	Item no.942-042,944-043 and 942-067 are discontinued

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EC Declaration of Conformity

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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: Casper Folsing Date: 25-May-2022