

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

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

To whom it may concern





### RADIOMETER MEDICAL ApS



To whom it may concern

International Sales Division

Akandevej 21

DK-2700 · Brønshøj · Denmark Phone: +45 38 27 38 27 Phone (dir.): +45 38 27 21 64 Fax: +45 38 27 27 11 CVR No.: 13496188 e-mail: rint@rint.dk

November 9, 2007 SKV

http://www.radiometer.com

#### Declaration about secure use of Radiometer equipment

Radiometer analyzers are made by using the most advanced production methods. The equipment are developed and tested together with the original Radiometer consumable items like electrodes, membranes, reagents and only exact tolerances are accepted.

It is a known clinical fact that accurate blood gas results are crucial when used as diagnostic tools. In fact, it is better to have <u>no</u> blood gas result than to have an inaccurate result.

In order to guarantee proper and secure results from the analyzer only the original Radiometer consumable must be used.

Besides that above mentioned, numerous problems may arise from using non-Radiometer consumable items on the Radiometer blood gas analyzers (ABL series), and as such we must emphasize the importance of using only Radiometer consumable items on the analyzers.

Below is a general list of problems that may be caused by the use of non-Radiometer consumable items. This is a general and it applies to most Radiometer analyzers.

- 1. Inaccuracy and Imprecision
- 2. Carry-over between measurements
- 3. Destruction of enzyme
- 4. Deposits/precipitation, clogging
- 5. High drift on calibrations
- 6. Decreased analyzer performance, long downtime, shorter lifetime, invalid results and repeated measurements
- 7. Excessive control ranges on QC
- 8. Lost confidence and repeat measurements
- 9. Increased yearly cost

Remember that patient safety is the most important area in modern health care, and among the critically ill patients the accurate blood gas results are necessary.





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#### Декларация о надежном использовании оборудования Radiometer

Анализаторы фирмы Radiometer создаются при использовании самых передовых методов производства. Оборудование разрабатывается и тестируется вместе с оригинальными расходными материалами фирмы Radiometer, такими как электроды, мембраны, реактивы, и принимаются только точные допуски.

Это известный клинический факт, что точные результаты газов крови являются решающим фактором когда используются в качестве диагностических инструментов. Фактически, лучше не иметь никакого результата газов крови чем иметь неточный результат.

Чтобы гарантировать точные и надежные результаты выдаваемые анализаторами, необходимо использовать только оригинальные расходные материалы фирмы Radiometer.

Помимо вышеупомянутого, в результате использования на газовых анализаторах фирмы Radiometer (серии ABL) расходных материалов других фирм (Non-Radiometer) могут возникнуть многочисленные проблемы, и в связи с этим мы должны подчеркнуть важность использования на анализаторах только расходных материалов фирмы Radiometer.

Ниже приведен общий перечень проблем, которые могут быть вызваны использованием расходных материалов других фирм (Non-Radiometer). Это общие проблемы и они относятся к большинству анализаторов фирмы Radiometer.

- 1. Отклонение и неточность в результатах
- 2. Остаток между измереними искажающий результаты
- 3. Разрушение фермента
- 4. Осадок/осаждение, загрязнение
- 5. Высокий дрейф при калибровках
- 6. Снижение производительности анализатора, длительный простой, укороченный жизненный цикл, неверные результаты и повторные измерения
- 7. Завышенние контрольного диапазона при проведении Контроля Качества
- 8. Потеря уверенности в результатах и повторение измерений
- 9. Увеличение ежегодных затрат

Помните, что безопасность пациентов является наиболее важным направлением в современном медицинском здравоохранении, и для пациенты находящиеся в критическом состоянии нуждаются в получении точных результатов газов крови.

Best regards RADIOMETER MEDICAL ApS International Sales Division

Simon Kvetny Regional Manager

Перевод с английского языка на русский язык проверен штатным переводчиком Отдела переводов Торгово-промышленной Палаты Республики Молдова с 10036000

Натальей Пясецкой Кишинэу/ Молдова, 03.11.2008 г.

### 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:	nex II/List B
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ABL800 FLEX - Solutions Product family:

	Ref. No.	GMDN	CE-mark
Name	944-126	30210	2008-12
S8375 Cleaning solution with additive	944-128	35933	2004-12
S1820 Calibration solution 1	944-129	35933	2004-12
S1830 Calibration solution 2	944-132	30210	2004-12
S4980 Rinse solution	944-133	35933	2006-11
S1827 Calibration Solution 1	944-134	35933	2006-11
S1837 Calibration Solution 2	944-136	30210	2006-11
S8377 Cleaning Met II Solution	944-159	30210	2006-11
S4987 Rinse solution II	1944-133	JOLIV	

Issuance:

Name: Gitte Juel Friis

Title:

Director Regulatory Affairs

hive full Im

Place:

Copenhagen, Denmark

Signature:

Date: 2014-03-25

Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)			
S5362 Hypochlorite Solution			
REF 943-906 from LOT NE-01 and onward			
complies with the provisions in the directive:			
98/79/EC (IVDD) Annex III			
Issued (place): Copenhagen			
Date: December 4, 2003 by:	Kirsten Rønø		
	Director of Quality		
Signature:	Just Parp		

F1544, udg. 2, IS 62-00-001







#### 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 E
	☐ Self-testing	☐ Performance Eval	uation

Product family: ABL700 and ABL800 series

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
ctHb Calibration Solution	S7770	944-021	35933	Lot 30 onward

<sup>\*:</sup> According to the nomenclature provided in ISO/TS-20225

#### Notified Body:

As specified in the Directive and Annex mentioned above, the conformity assessment procedure for this class of product does not require the involvement of a Notified Body.

#### Issuance:

Name: Rierr

Rierre Pelletier

Place: Copenhagen, Denmark

Title:

Regulatory Affairs Manager

Date: 2007-10-22

Signature:

F1543 Rev. 7

Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsib	takes responsibility in declaring that the following product(s)		
S7745 AutoCheck	k5+ – Level 2		
REF 944-075 from	m LOT 72 and onward		
delivered from Radiometer Medical A/S after 2003-10-27, complies with the provisions in the directive:			
98/79/EC (IVDD	) Annex III		
Issued (place):	Copenhagen		
Date:	December 4, 2003 by: Kirsten Rønø		
	Director of Quality		
	Signature: Just Parp		





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)			
D711 Membrane	box for E1001 electrode – Ref		
REF 942-058 from	n LOT 194 and onward		
complies with th	complies with the provisions in the directive:		
98/79/EC (IVDD)	Annex III		
Issued (place):	Copenhagen		
Date:	December 4, 2003 by:	Kirsten Rønø	
		Director of Quality	
	Signature:	Just Parp	





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)		
D788 Membrane	box for E788 electrode – pCO <sub>2</sub>	
REF 942-063 from	n LOT 65 and onward	
complies with th	e provisions in the directive:	
98/79/EC (IVDD)	Annex III	
Issued (place):	Copenhagen	
Date:	December 4, 2003 by:	Kirsten Rønø
		Director of Quality
	Signature:	Just Parp





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)			
D799 Membrane	box for E799 electrode – $pO_2$		
REF 942-064 from	n LOT 56 and onward		
complies with th	e provisions in the directive:		
98/79/EC (IVDD)	Annex III		
Issued (place):	Copenhagen		
Date:	December 5, 2003 by:	Kirsten Rønø	
	_	Director of Quality	
	Signature:	Just Parp	





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)				
D722 Membrane	box for E722 electrode – K <sup>+</sup>			
REF 942-059 from	m LOT 66 and onward			
complies with th	complies with the provisions in the directive:			
98/79/EC (IVDD)	) Annex III			
Issued (place):	Copenhagen			
Date:	December 4, 2003 by:	Kirsten Rønø		
		Director of Quality		
	Signature:	Just Parp		





Radiometer Medical ApS Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)		
D755 Membrane	pox for E755 electrode – Na <sup>+</sup>	
REF 942-062 from	n LOT 63 and onward	
delivered from Radiometer Medical ApS after 2003-12-07, complies with the provisions in the directive:		
98/79/EC (IVDD)	Annex III	
Issued (place):	Copenhagen	
Date:	February 18, 2004 by: Kirsten Rønø	
	Director of Quality	
	Signature: Desp	





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)			
D744 Membrane	box for E744 electrode – Cl		
REF 942-061 from	m LOT 42 and onward		
complies with the provisions in the directive:			
98/79/EC (IVDD) Annex III			
Issued (place):	Copenhagen		
Date:	December 4, 2003 by:	Kirsten Rønø	
		Director of Quality	
	Signature:	Just Parp	





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)			
D733 Membrane box for E733 electrode – Ca <sup>2+</sup>			
REF 942-060 from LOT 55 and onward			
complies with the provisions in the directive:			
98/79/EC (IVDD) Annex III			
Issued (place):	Copenhagen		
Date:	December 4, 2003 by:	Kirsten Rønø	
		Director of Quality	
	Signature:	This Parp	





Radiometer Medical A/S Åkandevej 21 DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)				
D7066 Membrane box for E7066 electrode – Glu				
REF 942-065 from LOT 243 and onward				
complies with the provisions in the directive:				
98/79/EC (IVDD) Annex III				
Issued (place):	Copenhagen			
Date:	December 4, 2003 by:	Kirsten Rønø		
		Director of Quality		
	Signature:	Just Porp		



