

Product name:	Radiometer SDS M1 044	Page:	1/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

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## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name: Radiometer SDS M1 044  
Product name: Product specification see section 16.

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Application: Radiometer Samplers.

### 1.3. Details of the supplier of the safety data sheet

Manufacturer: Radiometer Medical ApS  
Åkandevvej 21  
DK-2700 Brønshøj, DENMARK  
Tel: +45 3827 2853  
Tel: +45 3827 2828  
www.radiometer.com

Responsible for safety data sheet authoring: environment@radiometer.dk

### 1.4. Emergency telephone number

Emergency telephone: Poison Control Centers may be available in specific member countries.

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

The product is not classified.

### 2.2. Label elements

The substance/mixture does not meet the criteria for classification and labelling.

### 2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2. Mixtures

The product contains: Filter paper with heparin 60 - 80 IU and salts.  
After sterilization the residuals of ethylene oxide in SafePICO samplers are below 2,000 µg/device.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	2/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

---

## SECTION 4: FIRST AID MEASURES

### **4.1. Description of first aid measures**

Not relevant during normal use. In case of breakage of the packaging:

Inhalation: Not relevant.  
Skin contact: Wash skin with soap and water.  
Eye contact: Rinse with water.  
Ingestion: Rinse mouth and drink plenty of water.

### **4.2. Most important symptoms and effects, both acute and delayed**

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

### **4.3. Indication of any immediate medical attention and special treatment needed**

Medical attention/treatments: Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### **5.1. Extinguishing media**

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

### **5.2. Special hazards arising from the substance or mixture**

Specific hazards: No specific precautions.

### **5.3. Advice for firefighters**

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### **6.1. Personal precautions, protective equipment and emergency procedures**

Personal precautions: Avoid contact with skin and eyes.

### **6.2. Environmental precautions**

Environmental precautions: Not relevant considering the small amounts used.

### **6.3. Methods and material for containment and cleaning up**

Methods for cleaning up: Collect in marked containers and deliver to approved depot.

### **6.4. Reference to other sections**

References: For personal protection, see section 8.  
For waste disposal, see section 13.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	3/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

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## SECTION 7: HANDLING AND STORAGE

### **7.1. Precautions for safe handling**

Safe handling advice: No special precautions when handling undamaged units.  
Damaged units: Observe good chemical hygiene practices. Avoid contact with skin and eyes.  
When product is in use it will contain human blood. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

### **7.2. Conditions for safe storage, including any incompatibilities**

Technical measures for safe storage: No special precautions.

Storage conditions: Store in a dark place. See storage temperature on the product label.

### **7.3. Specific end use(s)**

Specific use(s): Not relevant.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### **8.1. Control parameters**

No occupational exposure limit assigned.

### **8.2. Exposure controls**

Personal protection: No special precautions when handling undamaged units.  
Damaged units: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Hand protection: In case of contact with spilled product: Wear protective gloves.

Hygiene measures: Wash hands after handling.

Environmental Exposure Controls: Not available.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	4/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Appearance: Syringes. Capillary tubes.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting point / freezing point: Not available.

Boiling point: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Explosion limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Not applicable.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature (°C): Not available.

Decomposition temperature (°C): not relevant

Viscosity: Not available.

Oxidising properties: Not available.

### 9.2. Other information

Other data: Not available.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	5/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

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## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity: Not known.

### 10.2. Chemical stability

Stability: Stable under the prescribed storage conditions.

### 10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

### 10.4. Conditions to avoid

Conditions/materials to avoid: None specific.

### 10.5. Incompatible materials

Incompatible materials: Not known.

### 10.6. Hazardous decomposition products

Hazardous decomposition products: None under normal conditions.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Skin contact: Damaged units: Prolonged or repeated contact may cause irritation.

Eye contact: Damaged units: Direct contact may irritate.

Ingestion: Not likely, due to the form of the product.

Specific effects: None known.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	6/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

---

## SECTION 12: ECOLOGICAL INFORMATION

### **12.1. Toxicity**

Ecotoxicity: The product is not expected to be hazardous to the environment.

### **12.2. Persistence and degradability**

Degradability: There are no data on the degradability of this product.

### **12.3. Bioaccumulative potential**

Bioaccumulative potential: No data available on bioaccumulation.

### **12.4. Mobility in soil**

Mobility: Not relevant, due to the form of the product.

### **12.5. Results of PBT and vPvB assessment**

PBT/vPvB: This product does not contain any PBT or vPvB substances.

### **12.6. Other adverse effects**

Other adverse effects: None known.

## SECTION 13: DISPOSAL CONSIDERATIONS

### **13.1. Waste treatment methods**

Dispose of waste and residues in accordance with local authority requirements.

NOTE: When product is in use it will contain human blood. Observe routine biosafety procedures in handling the product and consider all materials as potentially infectious.

Waste from residues: EWC-code: 18 01 01 or 18 01 03

Contaminated packaging: Dispose of contaminated packings as residue.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	7/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

---

## SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

### **14.1. UN number**

UN-No: -

### **14.2. UN proper shipping name**

Proper Shipping Name: -

### **14.3. Transport hazard class(es)**

Class: -

### **14.4. Packing group**

PG: -

### **14.5. Environmental hazards**

Marine pollutant: -

Environmentally Hazardous substance: -

### **14.6. Special precautions for user**

Special precautions: None known.

### **14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code**

Transport in bulk: Not relevant.

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	8/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

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## SECTION 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

### 15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

## SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 1, 2, 3, 4, 5, 8, 9, 11, 12, 13, 15, 16.

This SDS refers to the following internal drawings:

942-894: A4-33661 rev 8  
942-895: A4-33661 rev 8  
942-896: A4-33661 rev 8  
942-897: A4-33661 rev 8

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	9/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

---

942-899: A4-33661 rev 8  
942-965: DRW-001183 rev 7  
942-966: DRW-001184 rev 8

Standard Operating Procedure #3005 from Celsus regarding Heparin Sodium - Specifications (10/14/09)  
Standard Operating Procedure #3007 from Celsus regarding Heparin Sodium Solution (PU) (10/14/09)  
Standard Operating Procedure #3075 from Celsus regarding Heparin Lithium - Specifications (06/01/08)  
Radiometer SafePICO Certificate (BKH/20-09-2010)

## Product specification:

956-518 PICO70 Self-filling arterial blood sampler  
956-519\* PICO70 Self-filling arterial blood sampler  
956-522 PICO70 22gx25mm Arterial blood sampler w. 22gx25mm needle, 1.5 mL, box of 100 pcs  
956-525 Arterial Blood Sampler PICO70 with needle, 22G x 32 mm  
956-529 Arterial Blood Sampler PICO70 with needle, 23G x 16 mm  
956-533 Arterial Blood Sampler PICO70 with needle, 23G x 25 mm  
956-534 Arterial Blood Sampler PICO70 with needle, 23G x 32 mm  
956-547 Arterial Blood Sampler PICO70 with needle, 25G x 16 mm  
956-552 PICO50 Arterial blood sampler, Aspirator  
956-608\* safePICO70 + (nsd) 22G x 32 mm  
956-609\* safePICO70 + (nsd) 23G x 16 mm  
956-610\* safePICO Self-fill, self-filling arterial sampler  
956-612 safePICO 23G x 16 mm  
956-613 safePICO 22G x 25 mm  
956-614\* safePICO + (nsd) 22G x 32 mm  
956-615\* safePICO + (nsd) 23G x 16 mm  
956-616\* safePICO + (nsd) 23G x 25 mm  
956-620\* safePICO + (nsd) 22G x 25 mm  
956-622 safePICO Aspirator, arterial blood sampler  
956-623 safePICO + (nsd) 25G x 16mm  
956-624\* safePICO70 + (nsd) 23G x 25 mm  
956-634\* safePICO70 + (nsd) 23G x 32 mm  
956-635\* safePICO + (nsd) 23G x 32 mm  
956-636 safePICO 23G x 25 mm  
956-637 safePICO 23G x 32 mm

\* No needle cube

(nsd) = needle shield device

905-954 CLINITUBES, D956G-70-45 (1 x 70 x 45 µL)  
905-661 CLINITUBES, D956G-70-35 (1 x 75 x 35 µL)  
905-663 CLINITUBES D956G-70-100X1  
905-664 CLINITUBES D956G-70-125X1  
905-666 CLINITUBES D956G-70-210X1  
942-868 CLINITUBES D957G-70-35  
942-869 D957G-70-35x5 CLINITUBES 5 vials of 75 units. 35 µL. Multipack w. accessories  
942-872 CLINITUBES D941G-240-55  
942-873 CLINITUBES D941G-NA-240-55X10  
942-874 CLINITUBES D941G-240-85  
942-875 CLINITUBES D941G-240-85X5  
942-876 CLINITUBES D941G-NA-240-85X10  
942-877 CLINITUBES D957G-70-100  
942-878 CLINITUBES D957G-70-100x5 with balanced heparin, 100 µL

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# SAFETY DATA SHEET

Product name:	Radiometer SDS M1 044	Page:	10/10
Supersedes date:	2015-06-08	Revision:	2019-02-11
Product No.:	See Section 16	SDS-ID:	EU-EN/4.0

---

942-879 CLINITUBES D957G-70-125  
942-880 CLINITUBES D957G-70-125x5 with balanced heparin, 125 µL  
942-881 CLINITUBES D941G-80-140  
942-882 CLINITUBES D941G-80-140X5  
942-884 CLINITUBES D957G-70-210X5  
942-885 CLINITUBES D941G-240-55X5 with sodium heparin, 55 µL  
942-889 safeCLINITUBES D941P-NA-240-55X3  
942-890 safeCLINITUBES, D941P-240-85 (1 x 250 x 85 µL)  
942-891 safeCLINITUBES, D941P-NA-240-85 (3 x 250 x 85 µL)  
942-892 safeCLINITUBES, D957P-70-100 (1 x 250 x 100 µL)  
942-893 safeCLINITUBES, D957P-70-125 (1 x 250 x 125 µL)  
942-894 safeCLINITUBES D941P-240-55  
942-895 safeCLINITUBES D941P-240-85  
942-896 safeCLINITUBES D957P-70-100  
942-897 safeCLINITUBES D957P-70-125  
942-898 safeCLINITUBES, D957P-70-70 (1 x 250 x 70 µL)  
942-899 safeCLINITUBES D957P-70-70  
942-965 CLINITUBES D957G-70-45  
942-966 safeCLINITUBES D957P-70-45  
942-968 CLINITUBES D957G-70-45X5  
942-969 safeCLINITUBES D957P-70-45X1

Abbreviations and acronyms PBT = Persistent, Bioaccumulative and Toxic.  
used in the safety data sheet: vPvB = very Persistent and very Bioaccumulative.

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The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Artensvej 5, DK-2970 Hørsholm, Denmark.  
[www.dhigroup.com](http://www.dhigroup.com).

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