

EU Declaration of Conformity

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	SRN: DK-MF-000016271
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We, Radiometer Medical ApS, declare with the issue of this Declaration of Conformity, that we as manufacturer take 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) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, as specified in annex IV.

Classification:

Class IIa
 Class IIb
 Class III

Product family: PICO70, safePICO70 and safePICO Self-fill with needle

Table 1 PICO70

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
PICO70	22Gx25 mm: 956-522 22Gx32 mm: 956-525 23Gx16 mm: 956-529 23Gx25 mm: 956-533 25Gx16 mm: 956-547	57006900009MT	A02010502	31336
Intended purpose				
Preheparinized, electrolyte-balanced, arterial blood syringe product line for collection of arterial samples for pH, blood gas, oximetry, electrolyte and metabolite analysis.				

Table 2 safePICO70

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
safePICO70	22Gx32 mm: 956-608 23Gx16 mm: 956-609 23Gx25 mm: 956-624 23Gx32 mm: 956-634	57006900010MC	A02010502	31336
Intended purpose				
The safePICO70 self-fill syringe is an arterial blood syringe for pH, blood gas, oximetry, electrolyte, and metabolite analysis.				

Table 3 safePICO Self-Fill

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
safePICO Self-Fill	23Gx16 mm: 956-612 22Gx25 mm: 956-613	57006900011ME	A02010502	31336
safePICO Self-Fill	22Gx32 mm: 956-614 23Gx16 mm: 956-615 23Gx25 mm: 956-616 22Gx25 mm: 956-620 25Gx16 mm: 956-623 23Gx32 mm: 956-635	57006900012MG	A02010502	31336
Intended purpose				
The safePICO Arterial Blood syringe is a preheparinized, electrolyte-balanced, arterial blood syringe for collection of arterial samples for pH, blood gas, oximetry, electrolyte, and metabolite analysis.				

Conformity Assessment based on a quality management system and on assessment of technical documentation as described in Annex IX.

MDR Certificate #: MDR 724885

Issued by Notified Body: BSI Group, The Netherlands B.V.

Notified Body #: 2797

Common specifications:

currently non-applicable

Date of the first issuance of the EU Declaration of Conformity: 2022-09-13 (MDR)

Issuance:


Signature

Copenhagen, Denmark
Issued in

04-Oct-2022
Date


Name

Director, RA
Position

1 Change History

Revision	Author	Change Description
1	BENKJ	Document established
2	BENKJ	-Update due to new sterile barrier system for PICO70 (introduced as part of EC-005074). -New template for DoC is used (FRM-02587).
3	BENKJ	DoC updated according to new template (FRM-02587, rev 3)
4	BENKJ	DoC updated with SRN number, EMDN number and date of the first issuance
5	BENKJ	-Removal of PICO70 Ref. No. 956-534 from Table 1 due to discontinuation. -Corrected spelling mistake in Table 2: safePICO70 Ref. no. 956- 534 to 956- 634 .