

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 93/42/EEC of the European Council of June 14, 1993, concerning medical devices (MDD) as specified in Annex II.

Class: IIa IIb III

Product family: Arterial Blood Sampler with needle

Name	Ref No.	GMDN	CE-mark
safePICO 23Gx16 mm	956-612	31336	2006-04
safePICO 22Gx25 mm	956-613	31336	2006-04
safePICO 22Gx32 mm	956-614	31336	2006-04
safePICO 23Gx16 mm	956-615	31336	2006-04
safePICO 23Gx25 mm	956-616	31336	2006-04
safePICO 22Gx25 mm	956-620	31336	2006-04
safePICO 25Gx16 mm	956-623	31336	2006-04
safePICO 23Gx32 mm (Japan only)	956-635	31336	2006-04

Notified Body:

BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body No.: 2797

Issuance:

Name: Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature: 

Date: 2019-02-28

1 Change History

Revision	Author	Change Description
001	ZAL	New form(02233/1) is implemented
002	ZAL	New notified body number and address implemented