

# 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 <sub>2</sub>	962-045	52859	2003-12
Gas 1 – Gas Mixture – N <sub>2</sub> CO <sub>2</sub> O <sub>2</sub>	962-140	52859	2003-12
Gas 2 – Gas Mixture – N <sub>2</sub> CO <sub>2</sub>	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

## 1 Change History

<b>Revision</b>	<b>Author</b>	<b>Change Description</b>
01	ZAL	New form is implemented
02	ZAL	Item number 962-109 is discontinued