

EC Declaration of Conformity

Radiometer Medical ApS

Åkandevvej 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: Electrodes

Name	Ref. No.	GMDN	CE-mark
E1001 Reference Electrode for ABL analyzers – Ref	945-603	59241	2003-12
E788 Electrode for ABL analyzers – $p\text{CO}_2$	945-612	54500	2004-02
E799 Electrode for ABL analyzers – $p\text{O}_2$	945-613	54501	2003-12
E777 Electrode for ABL analyzers – pH	945-614	54499	2004-06
E722 Electrode for ABL analyzers – K^+	945-615	52892	2003-12
E733 Electrode for ABL analyzers – Ca^{2+}	945-616	52874	2003-12
E744 Electrode for ABL analyzers – Cl^-	945-617	52876	2003-12
E755 Electrode for ABL analyzers – Na^+	945-618	52896	2003-12
E7077 Electrode for ABL analyzers – Lactate	945-619	30208	2003-12
E7066 Electrode for ABL analyzers – Glucose	945-620	53303	2003-12
E8088 CREA A Electrode	945-662	53252	2006-11
E8089 CREA B Electrode	945-663	53252	2006-11

Issuance:

Name: Anna Jessen

Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature:



Date:

14.04.2021

1 Change History

Revision	Author	Change Description
01	ZAL	New form is implemented
02	ZAL	Item number 945-375, 945-383, 945-433, 945-434, 945-435, 945-450, and 945-600 are discontinued
03	ZAL	Item 945-633 is discontinued
04	ZAL	Item 945-376 is discontinued
05	ZAL	Item 945-599 is discontinued
06	ZAL	Item number 945-737 is discontinued