

# 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:**        Glass capillaries for blood sampling

| Name                       | Ref. No. | GMDN  | CE-mark |
|----------------------------|----------|-------|---------|
| Clinitubes D956G-70-45     | 905-954  | 61419 | 2014-11 |
| Clinitubes D956G-70-35     | 905-661  | 61419 | 2002-02 |
| Clinitubes D956G-70-100    | 905-663  | 61419 | 2002-01 |
| Clinitubes D956G-70-125    | 905-664  | 61419 | 2002-02 |
| Clinitubes D956G-70-210    | 905-666  | 61419 | 2002-01 |
| Clinitubes D957G-70-35     | 942-869  | 61419 | 2002-01 |
| Clinitubes D941G-NA-240-55 | 942-873  | 61387 | 2002-01 |
| Clinitubes D941G-240-85    | 942-875  | 61387 | 2002-01 |
| Clinitubes D941G-NA-240-85 | 942-876  | 61387 | 2002-01 |
| Clinitubes D957G-70-100    | 942-878  | 61419 | 2002-01 |
| Clinitubes D957G-70-125    | 942-880  | 61419 | 2002-01 |
| Clinitubes D941G-80-140    | 942-882  | 61387 | 2002-01 |

| Name                    | Ref. No. | GMDN  | CE-mark |
|-------------------------|----------|-------|---------|
| Clinitubes D957G-70-210 | 942-884  | 61419 | 2002-01 |
| Clinitubes D941G-240-55 | 942-885  | 61387 | 2002-01 |
| Clinitubes D957G-70-45  | 942-968  | 61419 | 2014-11 |

**Issuance:**

Name: Gitte Juel Friis

Place: Copenhagen, Denmark

Title: Senior Director Regulatory Affairs

Signature:



Date:

2009-01-26

**1 Change History**

| Revision | Author | Change Description   |
|----------|--------|--|
| 1        | ZAL    | New form is implemented  |
| 2        | ZAL    | Item no.942-873 and item no. 942-876: NA (Natrium = Sodium) has been added<br>Item no.942-968: D956G is corrected to D957G |