EC Certificate
Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 842	aur2a1909v110f699	2019-09-29	2024-05-27	2014-10-15

This is to certify that the quality system of:

Rønvig Dental Manufacturing A/S
Gl. Vejlevej 59
8721 Daugaard
Denmark

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II.

The certificate covers the following devices:

Design, manufacture and final inspection of ceramic tissue trimmers, dental injection systems and dental micro-blasters in class IIa

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S.
This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex II, section 5.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Bent Buus
Authorized person
For Presafe Denmark A/S