

		EC Declaration of Conformity		Page 1 of 1
Product:		Calaject		Version: 03
Doc. no.: Calaject-DoC		Author: EH	Approved by: ARN	Date: 2019-09-19
File name: DoC Calaject Version 03				

Identification of the Legal Manufacturer:	RØNVIG Dental Manufacturing A/S Gl. Vejlevej 59 8721 Daugaard Denmark
Identification of Authorized Representative:	RØNVIG Dental Manufacturing A/S Gl. Vejlevej 59 8721 Daugaard Denmark
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Identification of the device(s) concerned:	REF 2111, 2116 & 2126 Calaject™
Risk Classification:	Class II a as per Rule 11 in Annex IX
We hereby declare that the above-mentioned devices comply with the European Medical Devices Directive 93/42/EEC as modified by 2007/47/EC.	
Name and address of Notified Body:	DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway
Applicable CE Certificate(s):	EC Quality System Certificate No. DGM-917, issued by Presafe Denmark, Notified Body Number 0543, in accordance with Annex II Section 3.2 and 3.3 of this Directive.
	EC Certificate No. 10000381165-PA-NA-DNK Rev 0.0, issued by issued by DNV, Notified Body Number 2460, in accordance with Annex II Section 4 of this Directive.
Date of first CE Marking (using NB # 0459):	2012.07.12 Addendum of the certificate No. 19808 rev. 2.
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Annette Ravn Nielsen  Signature: _____ Title: CEO Place of Issue: Daugaard, Denmark Date: 18/5-2021