

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
241262-2017-CE-NOR-PS rev 1.0

Project No.:  
PRJC-495902-2013-MSL-NOR

Valid Until:  
27 May 2024

This is to certify that the quality system of:

### **CMS Dental A/S**

Elmevej 8, 7870 Roslev, Denmark

For design, production and final product inspection/testing of:  
**Dental root canal filling materials**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE  
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
**Høvik, 29 January 2021**

For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**

**Palani Damodharan**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



Certificate No.:  
241262-2017-CE-NOR-PS rev 1.0

Project No.:  
PRJC-495902-2013-MSL-NOR

Valid Until:  
27 May 2024

**Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 147554-2013-CE-NOR-NA 1.0 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	17 Nov 2017
1.0	Change in name and address	12 April 2018
2.0	Re-certification	29 January 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Dental root canal filling materials	Soft-Core Regular One-Step Regular One-Step Obturator  Soft Core Obturator TF Adaptive Obturator TF Obturator K3/K3XF Obturator  Thermoobturator  F360 Fill Obturator Herofill  Thermo GP  VividEndoCore  Obturator Gutapercha Endogal	IIa

**Sites covered by this certificate**

Site Name	Address
CMS Dental A/S (Roslev)	Elmevej 8, 7870 Roslev, Denmark

Certificate No.:  
241262-2017-CE-NOR-PS rev 1.0

Project No.:  
PRJC-495902-2013-MSL-NOR

Valid Until:  
27 May 2024

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate