DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
241262-2017-CE-NOR-PS rev 1.0	PRJC-495902-2013-MSL-NOR	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 Janauary 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

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.:	Project No.:	Valid Until:
241262-2017-CE-NOR-PS rev 1.0	PRJC-495902-2013-MSL-NOR	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

By Royal Charter

Supplementary information to AR120 810099

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

CMS Dental A/S
Elmevej 8
7870 Roslev
Denmark

Date: 23 September 2024

Changes Approved:

Date	Reference Number	Action
23 September 2024	30185253	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of 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. Original NB Certificate Number: 241262-2017-CE-NOR-PS rev 1.0

Inspiring trust for a more resilient world.

23 September 2024

CMS Dental A/S
Elmevej 8
7870 Roslev
Denmark

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
241262-2017-CE-NOR-PS rev 1.0	AR120 810099	93/42/EEC Annex II excluding Section 4	30185253	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of 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. Original NB Certificate Number: 241262-2017-CE-NOR-PS rev 1.0

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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