The products presented by this declaration are in conformity with the listed regulations. The manufacturer is exclusively responsible for this declaration of conformity.

Manufacturer	
Name, registered trade name or registered trademark	CMS Dental A/S
Address	Elmevej 8, 7870 Roslev, Denmark
Single registration number (SRN)	DK-MF-000020260

Product Information	
Product description	Endodontic Obturators
Product and accessories trade names	See appendix List of products
Intended purpose	The Obturator is used for a permanent sealing and filling (obturation) of an endodontically shaped, cleaned, and irrigated root canal. The Obturator is used after initial sealing of the dentinal wall. The Endodontic Obturator is a carrier of biocompatible plastic coated with thermoplastic gutta percha. The Obturator is heated to soften the gutta percha. The Obturator is inserted into the root canal. Verification that the Obturator reaches the apex is done by radiograph. After verification the excess plastic carrier and gutta percha is removed.
Basis UDI-DI	5713223OBT2YF

Region	**Classification (Risk Class & Rule)**	**Regulation Conformity**
EU	Medical Device: Class IIa, rule 8.	European Medical Devices Directive 93/42/EEC - Annex II
USA	Medical Device: Class I, 872.3850 Gutta-Percha 510(K) Exempt	Code of Federal Regulations CFR 21 800-898 Medical Devices

Standard compliance	
ISO 6877:2021	Dentistry – Endodontic obturating materials
ISO 10993-1:2020	Biological evaluation of medical devices

Competent Authority Representative	
Notified Body	BSI
Notified Body ID	2797
Conformity assessment procedure	Medical Devices Directive 93/42/EEC - Annex II Quality Management System – Medical devices - ISO 13485:2016 & EN ISO 13485:2016
Identification of certificate(s)	EC Certificate – Full Quality Assurance System

Original Certificate	Issuer (NB ID)	Issued
241262-2017-CE-NOR-PS rev 1.0	DNV (2460)	2021-01-29

Extended Certificate	Issuer (NB ID)	Issued	Valid until
AR120 810099	BSI (2797)	2023-09-23	2028-12-31

Quality Management System – Medical devices

Certificate	Certificate no.	Issuer (NB ID)	Issued	Valid until
ISO 13485:2016 & EN ISO 13485:2016	MD 810095	BSI (2797)	2025-01-22	2028-01-22

We, the manufacturer, hereby declare that the listed products comply with the above-mentioned regulations, relevant product standards and their transposition into national laws of the member states into which we place the device.

Approval, on behalf of CMS Dental A/S		
Name / Title / Signature	Lisbeth Rose / Quality Assurance Director	
Place / Date of issue	Copenhagen / 2025-01-23	

Appendix – List of products

Products

Product and trade name	Item no.	GTIN/UDI	Eudamed DI (Basis UDI-DI)
Soft-Core Obturator #20	SCR6/20	05713223000393	5713223OBT2YF
Soft-Core Obturator #25	SCR6/25	05713223000409	5713223OBT2YF
Soft-Core Obturator #30	SCR6/30	05713223000416	5713223OBT2YF
Soft-Core Obturator #35	SCR6/35	05713223000423	5713223OBT2YF
Soft-Core Obturator #40	SCR6/40	05713223000430	5713223OBT2YF
Soft-Core Obturator #45	SCR6/45	05713223000447	5713223OBT2YF
Soft-Core Obturator #50	SCR6/50	05713223000454	5713223OBT2YF
Soft-Core Obturator #55	SCR6/55	05713223000461	5713223OBT2YF
Soft-Core Obturator #60	SCR6/60	05713223000478	5713223OBT2YF
One-Step Obturator #20	OSR20/20	05713223001789	5713223OBT2YF
One-Step Obturator #25	OSR20/25	05713223001796	5713223OBT2YF
One-Step Obturator #30	OSR20/30	05713223001802	5713223OBT2YF
One-Step Obturator #35	OSR20/35	05713223001819	5713223OBT2YF
One-Step Obturator #40	OSR20/40	05713223001826	5713223OBT2YF
One-Step Obturator #50	OSR20/50	05713223001833	5713223OBT2YF
One-Step Obturator #60	OSR20/60	05713223001840	5713223OBT2YF
One-Step Obturator #20-60	OSR20/20-60	05713223001857	5713223OBT2YF
One-Step Obturator #30-60	OSR20/35-60	05713223001864	5713223OBT2YF