

EU Declaration of Conformity

The products presented by this declaration is in conformity with the listed regulations. The manufacturer is exclusively responsible for this EU 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 intended use is permanent sealing and filling (obturation) of an endodontically prepared tooth. The product consists of a central plastic core covered with a thermoplastic gutta percha (GP) layer. The product is heated to soften the GP. The whole product is inserted into the root canal. Verification that the product reaches the apex is done by x-ray. The excess plastic and GP is then removed.
Risk class	Class IIa

Competent Authority Representative	
Notified Body	DNV Product Assurance AS
Eudamed Actor ID	2460
Conformity assessment procedure	Medical Devices Directive 93/42/EEC - Annex II Quality Management System – Medical devices - ISO 13485:2016/NS-EN ISO 13485: 2016
Identification of certificate(s)	<u>EC Certificate – Full Quality Assurance System</u> Certificate number: 241262-2017-CE-NOR-PS rev 1.0 Issue date: 29-01-2021 Valid until: 27-05-2024 Issued by: DNV <u>Quality Management System – Medical devices</u> Certificate: ISO 13485:2016 / EN ISO 13485:2016 Certificate number: 268826-2018-AQ-NOR-NA-PS Rev.1.0 Issue date: 30 September 2021 Valid until: 10 December 2024 Issued by: DNV

Standard compliance	
ISO 6877:2021	Dentistry – Endodontic obturating materials

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 / 02-11-2022	

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

Verifikation

Transaktion 09222115557480651055

Dokument

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