


Declaration of Conformity

This Declaration of Conformity covers the European Medical Device Directive 93/42/EEC. The information included in this declaration fulfills the requirements in Annex II. The devices covered by this declaration is in conformity with the listed regulation.

Product description	Soft-Core Obturator, One-Step Obturator
Product and accessories trade names	See appendix: List of products
Serial numbers	All products releases within the time period of the EC Certificate is covered by this declaration.
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.
Conformity assessment procedure	Medical Devices Directive 93/42/EEC, Annex II Class IIa
Identification of certificate(s)	<p><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 GL PRESAFE AS Notified body No.: 2460</p> <p><u>Quality Management System – Medical devices</u> 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 Notified Body No.: 2460</p>

Manufacturer	CMS Dental A/S
Address	Elmevej 8, 7870 Roslev, Denmark

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC and its relevant transposition into national laws of the member states into which we place the device. The manufacturer is exclusively responsible for the declaration of conformity.

Approval	
On behalf of CMS Dental A/S	
Signature	
Name / Function	Lisbeth Rose / Quality Director
Place	Copenhagen
Date of issue	2021-12-10

Appendix - List of products

Products

Product and trade name	Item no.
<u>Soft-Core Regular / Soft-Core Obturator</u>	
Soft-Core Obturator, #20, 6 pcs	SCR6/20
Soft-Core Obturator, #25, 6 pcs	SCR6/25
Soft-Core Obturator, #30, 6 pcs	SCR6/30
Soft-Core Obturator, #35, 6 pcs	SCR6/35
Soft-Core Obturator, #40, 6 pcs	SCR6/40
Soft-Core Obturator, #45, 6 pcs	SCR6/45
Soft-Core Obturator, #50, 6 pcs	SCR6/50
Soft-Core Obturator, #55, 6 pcs	SCR6/55
Soft-Core Obturator, #60, 6 pcs	SCR6/60
<u>One-Step Regular / One-Step Obturator</u>	
One-Step Obturator, #20, 20 pcs	OSR20/20
One-Step Obturator, #25, 20 pcs	OSR20/25
One-Step Obturator, #30, 20 pcs	OSR20/30
One-Step Obturator, #35, 20 pcs	OSR20/35
One-Step Obturator, #40, 20 pcs	OSR20/40
One-Step Obturator, #50, 20 pcs	OSR20/50
One-Step Obturator, #60, 20 pcs	OSR20/60
One-Step Obturator, #20-60, 20 pcs	OSR20/20-60
One-Step Obturator, #35-60, 20 pcs	OSR20/35-60

Document log

Version	Date	Approval	Change description
v10	20-01-2021	MS	Item number list updated.
v11	17-02-2021	MS	Customer item no. references added.
v12	18-05-2021	MS	MDD template updated to include intended purpose. Accessories added to certificate.
v13	10-12-2021	MS	Certificate updated with new ISO 13485 certificate number. Accessories is removed from certificate. Size Verifiers is now registered as Class I after MDR.