

Document Title	<h1>Declaration of Conformity</h1>	 CMS Dental	Template	Page
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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	Size Verifier
Product and accessories trade names	See appendix List of products
Intended purpose	The Size Verifier is intended to secure that there is enough space in the prepared root canal for the obturator to fit in. The Size Verifier is an accessory to the obturator product. It is a helpful tool for the Dentist but not a necessary tool to complete the root canal filling satisfactorily. It is NOT a measuring device.
Basis UDI-DI	5713223SZV15A

Region	Classification (Risk Class & Rule)	Regulation Conformity
EU	Medical Device: Class I, rule 5	European Medical Device Regulation 2017/745
USA	Medical Device: Class I	Code of Federal Regulations, CFR 21 800-898 Medical Devices

Standard compliance	
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 6877:2021	Dentistry – Endodontic obturating materials
ISO 2768-1:2002	General tolerances – Part 1: Tolerances for linear and angular dimensions without individual tolerance indications
ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

Competent Authority											
Name	Danish Medicines Agency, Pharmacovigilance & Medical Devices										
Address	Axel Heides Gade 1, 2300 Copenhagen S, Denmark										
Phone	+45 4488 9595										
EUDAMED Actor ID	DK-CA-042										
Conformity assessment procedure	<p>Medical Device Regulation 2017/745</p> <table><tr><td>Annex II (TD)</td><td>Annex III (PMS)</td><td>Annex IX, Chapter I (QMS)</td><td>Article 19/Annex IV (DoC)</td></tr></table> <p>Quality Management System – Medical devices</p> <table><tr><td>ISO 13485:2016 &amp; EN ISO 13485:2016</td></tr></table>	Annex II (TD)	Annex III (PMS)	Annex IX, Chapter I (QMS)	Article 19/Annex IV (DoC)	ISO 13485:2016 & EN ISO 13485:2016					
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Identification of certificate(s)	<p>Quality Management System – Medical devices</p> <table><thead><tr><th>Certificate</th><th>Certificate no.</th><th>Issuer (NB ID)</th><th>Issued</th><th>Valid until</th></tr></thead><tbody><tr><td>ISO 13485:2016 &amp; EN ISO 13485:2016</td><td>MD 810095</td><td>BSI (2797)</td><td>2025-01-22</td><td>2028-01-22</td></tr></tbody></table>	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
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ISO 13485:2016 & EN ISO 13485:2016	MD 810095	BSI (2797)	2025-01-22	2028-01-22							

CMS Dental, the manufacturer, hereby declares that the listed products manufactured after the release date of this declaration of conformity are covered by this declaration of conformity and 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 / 2025-01-27

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## Appendix – List of products

### Products

Product and trade name	Item no.	GTIN/UDI	EUDAMED DI (Basis UDI-DI)
Size Verifier #20	SSV6/20	05713223000553	5713223SZV15A
Size Verifier #25	SSV6/25	05713223000560	5713223SZV15A
Size Verifier #30	SSV6/30	05713223000577	5713223SZV15A
Size Verifier #35	SSV6/35	05713223000584	5713223SZV15A
Size Verifier #40	SSV6/40	05713223000591	5713223SZV15A
Size Verifier #45	SSV6/45	05713223000607	5713223SZV15A
Size Verifier #50	SSV6/50	05713223000614	5713223SZV15A
Size Verifier #55	SSV6/55	05713223000621	5713223SZV15A
Size Verifier #60	SSV6/60	05713223000638	5713223SZV15A