

# EU Declaration of Conformity


This EU Declaration of Conformity covers the European Medical Device Regulation 2017/745. 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	Size Verifiers
Product and accessories trade names	See Appendix - List of products
Intended purpose	<p>The Size Verifier is intended to secure that there is enough space in the prepared root canal for the obturator to fit in.</p> <p>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.</p> <p>It is NOT a measuring device.</p>
Risk class	Class I

Competent Authority	
Name	Danish Medicines Agency, Pharmacovigilance & Medical Devices
Eudamed Actor ID	DK-CA-042
Conformity assessment procedure	<p><u>Quality Management System – Medical devices</u></p> <ul style="list-style-type: none"><li>• ISO 13485:2016 / EN ISO 13485:2016</li></ul> <p><u>Medical Device Regulation 2017/745</u></p> <ul style="list-style-type: none"><li>• Annex II (TD)</li><li>• Annex III (PMS)</li><li>• Annex IX, Chapter I (QMS)</li><li>• Article 19/Annex IV (DoC)</li></ul>
Identification of certificate(s)	<p>Certificate: ISO 13485:2016 / EN ISO 13485:2016</p> <p>Certificate number: 268826-2018-AQ-NOR-NA-PS Rev.1.0</p> <p>Issue date: 30 September 2021</p> <p>Valid until: 10 December 2024</p> <p>Issued by: DNV (notified body no. 2460)</p>

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Regulation 2017/745 and its relevant 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 / 20-05-2022	

## 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