


Document Title	<b>Declaration of Conformity</b>	 <b>CMS Dental</b> <small>Our Innovation Your Success</small>	Template	Page
ID			TD-212-05-01	F-42 v.15

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

<b>Manufacturer</b>	
Name, registered trade name or registered trademark	CMS Dental A/S
Address	Elmevej 8, 7870 Roslev, Denmark


<b>Product Information</b>	
Product description	Endodontic Obturator Heater
Product and accessories trade names	See appendix List of products
Intended purpose	The intended purpose of the Endodontic Obturator Heater is softening of Endodontic Obturators prior to usage. The Obturators are heated in the heater to soften the material. The heater is only to be used with the endodontic obturator systems mentioned in the specific product manuals. The heater is only to be used in Dental clinics by Dental personnel.

<b>Regions</b>	<b>Classification</b>	<b>Regulation Conformity</b>
EU, USA	Electrical Equipment for Laboratory use.	Low Voltage Directive (LVD) (2014/35/EU) Electromagnetic Compatibility (EMC) 2014/30/EU

<b>Standard compliance</b>	
Electrical Equipment for Laboratory use.	IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
Electromagnetic compatibility (EMC)	IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
Restriction of Hazardous Substances (RoHS)	RoHS Directive 2011/65/EU Restriction of the use of certain hazardous substances in electrical and electronic equipment.
Waste Electrical and Electronic Equipment (WEEE)	WEEE Directive 2012/19/EU on waste electrical and electronic equipment.

<b>Assessment</b>										
Conformity assessment procedure	Laboratory Electrical Equipment <div style="border: 1px solid black; padding: 2px;">IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.</div>									
	Quality Management System – Medical devices <div style="border: 1px solid black; padding: 2px;">ISO 13485:2016 &amp; EN ISO 13485:2016</div>									
Identification of certificate(s)	Laboratory Electrical Equipment <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th><u>Certificate</u></th> <th><u>Certificate no.</u></th> <th><u>Issuer</u></th> <th><u>Issued</u></th> </tr> </thead> <tbody> <tr> <td>CB</td> <td>252597-70003389</td> <td>CSA Group</td> <td>2014-11-24</td> </tr> </tbody> </table>	<u>Certificate</u>	<u>Certificate no.</u>	<u>Issuer</u>	<u>Issued</u>	CB	252597-70003389	CSA Group	2014-11-24	
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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.

<b>Approval, on behalf of CMS Dental A/S</b>	
Name / Title / Signature	Lisbeth Rose / Quality Assurance Director
Place / Date of issue	Copenhagen / 2025-01-30
	

## Appendix – List of products

### Products

Product and trade name	Item no.	GTIN/UDI
Soft-Core Heater EU plug	SCDTO/EU	05713223002489
Soft-Core Heater AU plug	SCDTO/AU	05713223002496
Soft-Core Heater UK plug	SCDTO/UK	05713223002502
Soft-Core Heater US plug	SCDTO/US	05713223002519
One-Step Heater EU plug	OSDTO/EU	05713223002663
One-Step Heater AU plug	OSDTO/AU	05713223002670
One-Step Heater UK plug	OSDTO/UK	05713223002687
One-Step Heater US plug	OSDTO/US	05713223002694