

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 Obturator Heater
Product and accessories trade names	See appendix: List of products
Intended purpose	<p>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.</p> <p>The heater is only to be used in Dental clinics by Dental personnel.</p>

Assessment	
Conformity assessment procedure	<p><u>Laboratory Electrical Equipment</u> IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.</p> <p><u>Quality Management System – Medical devices</u> ISO 13485:2016/NS-EN ISO 13485: 2016</p>
Identification of certificate(s)	<p><u>Laboratory Electrical Equipment</u> DS/EN 61010-1:2010 CB certificate number: CB 252597-70003389 Issued by: CSA Group</p> <p><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 Notified Body No.: 2460</p>

We, the manufacturer, hereby declare that the listed products comply with the above-mentioned regulations 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.
Soft-Core Heater	SCDTO/AU
	SCDTO/EU
	SCDTO/UK
	SCDTO/US
One-Step Heater	OSDTE/EU
	OSDTE/US
	OSDTE/UK

Accessories

Product and trade name	Item no.
One-Step Tweezers 100 ^o	OSOTWE/100
One-Step Tweezers 100 ^o type 2	OSOTWE/100N
One-Step Tweezers 135 ^o	OSOTWE/135
One-Step Tweezers 135 ^o type 2	OSOTWE/135N