


EC Declaration of Conformity

This European Community Declaration of Conformity covers Electrical safety of Laboratory equipment. The products listed in this declaration are in conformity with the mentioned regulation.

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.</p> <p>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>
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> 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 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements 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.
Soft-Core	
Soft-Core Heater	SCDTO/AU
	SCDTO/EU
	SCDTO/UK
	SCDTO/US
One-Step	
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

Document log

Version	Date	Approval	Change description
v10	20-01-2021	MS	Item number list updated with new customers
v11	17-02-2021	MS	Customer item no. references added
v12	17-05-2021	MS	Accessories included
v13	10-12-2021	MS	Certificate updated with new ISO 13485 certificate number.