


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 deskription	Endodontic Obturator Heater
Product and 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/NS-EN ISO 13485: 2016 Certificate number: 268826-2018-AQ-NOR-NA-PS Rev. 0.0 Issue date: 11 December 2018 Valid until: 10 December 2021 Issued by: DNV GL Presafe AS 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 Manager
Place	Copenhagen
Date of issue	2021-02-05

Appendix

Brand	Obturator system	Product or trade name	Item no.
CMS	Soft-Core	Soft-Core Heater	SCDTO/AU
			SCDTO/EU
			SCDTO/UK
			SCDTO/US
		Soft-Core Intro	SCDTINT/AU/R20-30
			SCDTINT/EU/R20-30
			SCDTINT/US/R20-30
			SCDTINT/UK/R20-30
		Soft-Core Deluxe	SCDT-G
			SCDT-S
MicroMega	Herofill	Ovn separat	n/a
		Intro EU	20638001N
		Intro UK	20638002N
Dentalica	Thermo GP	Thermo GP Heater	212501
		Thermo GP introkit	212500
Kerr	SoftCore	Soft-Core Heater	065-0200
Brasseler	F360	F360 Fill Heater	044444KO
CMS	One-Step	One-Step Heater	OSDTO/EU
			OSDTO/US
			OSDTO/UK
		One-Step IntroKit	OSDTINT/EU/R20-60
			OSDTINT/UK/R20-60
			OSDTINT/US/R20-60
		One-Step DeLuxe	OSDT-G
Nueva Galimplants	Endogal	Endogal Heater Set	HOG