

# EU DECLARATION OF CONFORMITY

We hereby declare that the listed CE-marked products, specified in the product list in Annex I, conform to the regulations as listed below.

- Regulation (EU) 2017/745            Medical Devices Regulation (MDR)
- Directive 2011/65/EU                Restriction on Hazardous Substances (RoHS2)

We ensure and declare that the listed CE-marked products, falling within MDR risk class I according to classification rule 13, meet the provisions of the EU regulations which apply to them and comply with the required and approved technical documentation.

This Declaration of Conformity covers the products as specified in the product list below and is valid for all products concerned bearing the CE-marking and manufactured at the following site: Schansestraat 7-9, 4515 RN IJzendijke, The Netherlands.

## **Product identification**

Product:        Obturator Oven

Sample photograph:



Description:    Obturator Ovens are used to heat endodontic obturators for use in root canal therapy. The unit is equipped with two heaters which are temperature and time controlled. Heater circuitry turns off automatically after the heating cycle is ended. A temperature cut off mechanism prevents overheating.

The following list identifies the products that are delivered from September 2021:

Trade name	Type	Product code	Basic UDI-DI
Thermaprep	230V EU plug	B00THPR230VEU	87202993861HTR590004392
Thermaprep	230V UK plug	B00THPR230VUK	
Thermaprep	115V US plug	B00THPR115VUS	
GuttaFusion	230V EU plug	M00GFUS000000	

## **Authorization**

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Endotron B.V., Asveldweg 2, 7556 BP Hengelo, The Netherlands

Single Registration Number: NL-MF-000006005

Signed for and on behalf of Mr. A. Hamelink, COO

Hengelo, 26<sup>th</sup> of July 2021



Mr. N. Zeeders, Regulatory compliance officer