

Declaration of Conformity

European Communities Council Directive 93/42/EEC (MDD)
including revisions in 2007/47/EC Concerning Medical Devices



The undersigned declares that the products described in this document meet the
Council Directive provisions that apply to them and
the CE Mark may be affixed to:

P.O. Box 1548
Woodinville, WA 98072 USA
www.aseptico.com

info@aseptico.com

Telephone 800.426.5913
International 425.487.3157
Fax 360.668.8722

Product Reference: AEU-55 Calamus Dual with related accessories listed on page 2

Manufacturer: Aseptico Inc. 8333 216th Street SE
Woodinville, WA 98072 U.S.A

Variants: Annexed to this declaration when applicable.

Intended use: The Calamus Dual is intended for warm vertical obturation during Endodontic root canal filling.

**Medical Device Directive
Classification No:** *Classification and rules are identified on page 2*

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam

**European Authorized
Representative:** Advena Ltd.
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013
Malta

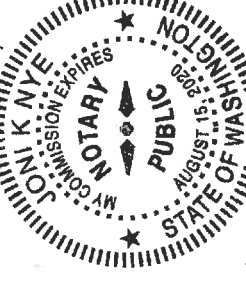
**Medical Device Directive
Assessment route:** Annex II point 3 full quality assurance. In conjunction with procedures based on EN ISO 13485:2016
-Medical Devices – Requirements for regulatory purposes.
Reference to EC certificate: **No 607775**

Signed:  Grant Ramamoorthy - Director of Regulatory Affairs

Date: 19-Jun-19

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed
on the market under the Aseptico Inc name regardless of whether these operations are carried out by the manufacturer or on his behalf
by a third party.

Quality Management Systems



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Continued

SKU	Product name	EU Classification (I, IIa, spare part, accessory...)	Annex IX Rule (if applicable)
A111000000000	Calamus Heated Plugger S	Class IIa	Rule 9 / Active therapeutic device, used on teeth (invasive through orifice...)
A112000000000	Calamus Heated Plugger M	Class IIa	Rule 9 / Active therapeutic device, used on teeth (invasive through orifice...)
A113000000000	Calamus Heated Plugger L	Class IIa	Rule 9 / Active therapeutic device, used on teeth (invasive through orifice...)
A115000000000	Calamus thermal response	Class IIa	Rule 9 / Active therapeutic device, used on teeth (invasive through orifice...)
A120800000000	Calamus Dual Hand Piece Cleaning Brush	Class I	Rule 1 / Non invasive accessory to a device
A121000000000	Calamus Dual Gutta-Percha Cartridges 20G	Class IIa	Rule 8 / Surgically invasive devices - Long term in teeth
A122000000000	Calamus Dual Gutta-Percha Cartridges 23G	Class IIa	Rule 8 / Surgically invasive devices - Long term in teeth
A130000000000	Calamus Dual	Class IIa	Rule 8 / Surgically invasive devices - Long term in teeth
A120600000000	Replacement Cartridge Nut	NMD	This is a "Replaceable Part" and not an "Accessory"
A120700000000	Cartridge Needle Bending Tool	Class I	Rule 1 / Non invasive devices
A120900000000	Hand Piece Heat Shield	Class I	Rule 1 / Invasive device, but not active

