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.

Product Reference:	AEU-65 Gutta Smart © Gutta Percha Delivery System
Manufacturer:	Aseptico Inc. 8333 216th Street SE Woodinville, WA 98072 U.S.A
Variants:	Annexed to this declaration when applicable.
Intended use:	Intended for endodontic treatment where a dentist fills/obturates a root canal with warm Gutta Percha
Medical Device Directive Classification No:	*For the overall system - See the attachment for other devices and accessories* II(a) Annex 9 Rule 9
Notified Body:	BSI Group Say Building John M Keynesplein 9 1066 EP Amsterdam, The Netherlands
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; Quality Management Systems -Medical Devices – Requirements for regulatory purposes. **Reference to EC certificate: No 607775**

Signed: Grant Ramaley - Director of Regulatory Affairs

Date: April 22th 2019

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.

Declaration of Conformity
Continued

Part/Device REF		Description
GSMART		Gutta-Smart Cordless Obturation System
GSMARTPACK		Gutta-Smart Pack Handpiece
GSEHPLRG		Gutta-Smart Electric Heat Plugger, Large
GSEHPMED		Gutta-Smart Electric Heat Plugger, Medium
GSEHPSML		Gutta-Smart Electric Heat Plugger, Small
GSTRTIP		Gutta-Smart Thermal Response Tip
GSMARTFLOW		Gutta-Smart Flow Handpiece
GSMART20G		Gutta-Smart Conform Fit GP Crtg 20G
GSMART23G		Gutta-Smart Conform Fit GP Crtg 23G
GSMART25G		Gutta-Smart Conform Fit GP Crtg 25G
GSMARTHE		Gutta-Smart Heating Elements
GSMARTBEND		Gutta-Smart Bending Tool
GSMARTCAP		Gutta-Smart Cleaning Cap
GSMARTRPC		Gutta-Smart Remote Power Cord