Aseptico
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This declaration of conformity is issued under the sole responsibility of Aseptico, Inc. in compliance to Article 19 of EU MDR 2017/745.

We hereby declare that the products described in this document meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of Aseptico, Inc.

Legal Manufacturer Name and address:	Aseptico, Inc. 8333 216TH Street SE Woodinville WA 98072 USA	
Single Registration Number:	**US-MF-000014012**	
Basic UDI-DI	++D099endotherapydeviceL2	
Product Name:	AEU-65 Gutta-Smart™ Cordless Obturation System	
Intended Use:	The AEU-65 is intended for warm vertical obturation during root canal therapy.	
EU MDR Classification:	MD Classification: IIa through Rule 9	Conformity Assessment Applied: ANNEX IX Chapters I and III
Variants:	See Appendix II— Product Listing	
EU Authorized Representative Information:	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta	
	SRN: **MT-AR-000000234**	
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands NB Number: 2797	
CE Certificate number: (If available)	MDR 765498 Expiry date: 2028-12-03	
Valid for:	1 Year	

Approval:

Name:	**[1]Function:**	**Signature and Place of Signature**	**Date**
Grant Ramaley	Director of Quality and Regulatory Affairs	Grant Ramaley Grant Ramaley (Dec 6, 2023 14:13 PST)	Dec 6, 2023

[1] Who has the responsibilities of the Person Responsible for Regulatory Compliance under the Aseptico, Inc. name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I— Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (As approved under AEU-65 List of Applicable Standards for MDR Revision B):

Standard Number/ Common Specification/ Document Name	Description
EN ISO 13485:2016	Medical devices – Quality management systems – System requirements for regulatory purposes
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 7000 / IEC 60417: Database	Graphical symbols for use on equipment
BS EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
EN 60601-1:2006/A1:2013	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
AAMI ES60601-1:2005/(R)2012	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (with amendments)
CAN/CSA-C22.2 No. 60601-1:14 (R2018)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 80601-2-60: 2012 (Ed 1.0)	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
IEC 60601-1-6:2010+A1:2013 (Ed 3.1)	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential Performance – Collateral standard: Usability
IEC 62366:2007+A1:2014 (Ed. 1.1)	Medical Devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-2:2014 (Ed. 4.0)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 62304:2006 (First Edition) + A1:2015)	Medical device software - Software life-cycle processes
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices.

Appendix II— Product Listing

Part Number/ Catalogue Number	Customer Reference Number	Description Name	EMDN Code		UDI-DI
			Code Number	Code description	
AEU-65-ROW	B00GSIQ000KIT	Gutta-Smart Cordless Obturation System	Q01010299	DENTAL DEVICE, Canal filling - OTHERS	+D099B00GSIQ000KIT0
AA-65BASE-ROW	B00GSIQ000BAS	Gutta-Smart Base Station	Component of the system		+D099B00GSIQ000BAS0
GP-035CP-ROW	BNSGSIQA0020G	Gutta-Smart GP Crtg 20G 10-pack			+D099BNSGSIQA0020G0
GP-025CP-ROW	BNSGSIQA0023G	Gutta-Smart GP Crtg 23G 10-pack			+D099BNSGSIQA0023G0
GP-018CP-ROW	BNSGSIQA0025G	Gutta-Smart GP Crtg 25G 10-pack			+D099BNSGSIQA0025G0
EHP2-60A-ROW	B00GSIQ100LRG	Gutta-Smart Electric Heat Plugger, Large			N/A
EHP2-50A-ROW	B00GSIQ100MED	Gutta-Smart Electric Heat Plugger, Medium			N/A
EHP2-40A-ROW	B00GSIQ100SML	Gutta-Smart Electric Heat Plugger, Small			N/A
EHP2-TR-ROW	B00GSIQ100000	Gutta-Smart Thermal Response Tip			N/A
HTR-ROW	BCPGSIQ000HES	Gutta-Smart Flow Heater			N/A
AA-65PACK-ROW	BCPGSIQ000PAK	Gutta Smart Pack Handpiece			N/A
AA-65FLOW-ROW	BCPGSIQ000FLO	Gutta Smart Flow Handpiece			N/A

Part Number/ Catalogue Number	Customer Reference Number	Description Name	EMDN Code		UDI-DI
			Code Number	Code description	
330801-ROW	BSPGSIQ000001	Gutta-Smart Charger Base			N/A
330800-ROW	BSPGSIQ000002	Gutta-Smart Charger top with LCD			N/A
850056-ROW	BSPGSIQ000003	Gutta-Smart Charger Feet			N/A
AA-65BEND-ROW	BCPGSIQ000BET	Gutta-Smart Cannula Bender			N/A
AA-65CAPS-ROW	BCPGSIQ000CAP	Gutta-Smart Cleaning Caps			N/A
AA-65PWRS-ROW	BCPGSIQ000RPC	Gutta-Smart Remote Power Cord			N/A

Revision History

Revision	Name	Date:	Change Description
A	Maria Osborne	12/06/2023	Initial Release based on receipt of EU MDR certificate first issue dated 2023/12/04.

AEU-65_DoC_Rev A

Final Audit Report 2023-12-06

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