EU Quality Management Certificate

This is to certify that the company

Aseptico Inc.

8333 216th Street SE
Woodinville, WA 98072
United States of America

SRN: US-MF-000014012

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31622686 MDR2017Q
Certificate ID	1000266017
Effective date	2025-12-18
Expiry date	2030-09-17
Frankfurt am Main,	2025-12-18

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000014012
Certificate ID: 1000266017

Authorised Representative of the company:

Advena Ltd.

Tower Business Centre, 2nd Flr.
Tower Street, Swatar
BKR 4013 Malta

SRN: MT-AR-000000234

Device categories and variants covered by this certificate:

Device category:	MDA 0311 - Active non-implantable dental devices
Product name:	Gutta-Smart™ Cordless Obturation System Gutta Percha Corded Obturation System
Risk classification:	IIa
Basic-UDI-DI:	++D099endotherapydeviceL2
Intended purpose:	Intended for warm vertical obturation during root canal therapy. When used with the thermal response tip, it is intended for the determination of tooth response thermal stimulus.

Device category:	MDA 0311 - Active non-implantable dental devices
Product name:	GO Ultra-Portable Dental System
Risk classification:	IIa
Basic-UDI-DI:	081741702dentalunitsX4
Intended purpose:	To be used for endodontic and general dentistry applications.

Examinations and tests performed:
31622686_A215916MED dated 2025-08-22
31622686_ A217178MED Gutta-Smart™ Cordless / Gutta Perch Corded dated 2025-08-11

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-09-18	1000263850	Addition of GO Ultra-Portable Dental System