MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's Name: THE ALGER COMPANY, INC

Business Address: 320 Flightline, Lago Vista, Texas 78645, USA

Medical Device(s): Algerbrush Corneal Burr System
See attached schedule 1 for list of product codes

Classification: Class IIa

GMDN Code and Term: 42443 – Bur system, corneal, battery-powered

Scope of Application: All product supplied

Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied to the device. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

PRODUCTION QUALITY ASSURANCE

BSI (Notified Body Number 2797)
EC Certificate Annex V of the Directive 93/42/EEC on Medical Devices.
Certificate Number CE 687289

Advena Ltd (EU Rep)
Tower Business Centre
2nd Flr. Tower Street
Swatar, BKR 4013
Malta

Standards Applied: ISO 13485:2016
ISO 14971:2019

Authorised signatory:

Signature

John Alger Vice President

Name, Position

Jan 21, 2021

Date