EC Declaration of Conformity to:
Medical Devices Directive 93/42/EEC

Legal Manufacturer:	Alger Company Inc. 320 Flightline Lago Vista, TX 78645
Manufacturing Site:	Alger Company Inc. 320 Flightline Lago Vista, TX 78645
Device Description/Family:	Algerbrush II Corneal Burr System *(See attached Product Schedule)*
EC Product Classification:	Class IIa, Annex IX, Rule 9
GMDN:	42443 – Burr System, Corneal, battery powered

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Applied Standards and Directives:

Standard Reference	**Description**
IEC 60601-1:2005 +A1:2012 EN 60601-1:2006 +A1:2013	Medical Electrical Equipment, 3rd Edition – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-1:2000 EN 60601-1-1:2001	Medical electrical equipment, 2nd Edition – Part 1-1: General requirements for safety. Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 10993-1:2009, (R)2013 EN ISO 10993-1:2009	Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a Risk Management Process
IEC 62366-1:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
IEC 60601-1-6:2010+A1:2013	General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability Ed. 3.1
ISO 14971:2007 EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-

		acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
	ISO 15223-1:2016 EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – part 1: General Requirements
	ASTM D4169-014	Standard practice for Performance Testing of Shipping Containers and Systems
	MEDDEV 2.7.1 Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	ISO 13485:2016 EN ISO 13485:2016 + cor 12:2018	Medical devices – Quality Management Systems – Requirements for Regulatory Purposes
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Notified Body Number: 2797	
EU Rep	Advena Ltd. Tower Business Ctr. 2nd Flr., Tower Street Swatar, BKR 4013 Malta 44 1926 800 153	
CE Certificate Number:	*Annex V (EC Certificate No. 687289)*	
Date of issuance of original CE certificate:	23 January 2001	

STED / Technical File: 001 Issue Level: 01

Signed: John Alger John Alger

Date: January 24, 2020 Company Management Representative

Product Schedule
Algerbrush II Corneal Burr System

GMDN Number: 42443

Part Number	Description	EC Product Class
BR2-5	ALGERBRUSH II Corneal Rust Ring Remover BR2-5 (1/2mm)	IIa
BR2-1	ALGERBRUSH II Corneal Rust Ring Remover BR2-1 (1mm)	IIa
BRPT-RF	ALGERBRUSH II Diamond Instrument BRPT-RF (Fine Round)	IIa
BRPT-RM	ALGERBRUSH II Diamond Instrument BRPT-RM (Med Round)	IIa
BRPT-WF	ALGERBRUSH II Diamond Instrument BRPT-WF (Fine Wheel)	IIa
BRPT-WM	ALGERBRUSH II Diamond Instrument BRPT-WM (Med Wheel)	IIa