

The management system of

Davis Schottlander & Davis Ltd

Fifth Avenue, Letchworth Garden City, Herts, SG6 2WD UK

EC-DECLARATION OF CONFORMITY

Directive 93/42/EEC

Products in MDD Class IIa

It is hereby declared that the products listed below comply with the provisions of the EC Council Directive 93/42/EEC of June 14th 1993, Annex V, concerning medical devices (MDD), as amended by EC Council Directive 2007/47/EC, under the supervision of Notified Body number 0120, SGS United Kingdom Ltd, Unit 202B, Worle Parkway, Weston-Super-Mare, Somerset, BS22 0WA.

Classified under MDD Annex X, Rule 5

Schottlander Nylon & Bristle Brushes, Enigma High-Base, Pegasus Pourable Cold Cure Denture Base, Enigma Colour Tone, enigmalive+ Acrylic Teeth, Enigma Teeth, 4Natur Teeth, Natura Teeth, Croform Excel S1 Nickel Free Alloy.

Classified under MDD Annex X, Rule 6

Schottlander non-sterile diamond burs and Rotary Polishers.

Classified under MDD Annex X, Rule 8

Matchmate NP10, Matchmate NP20, Opus Silver, Opusfil Glass Ionomer Restorative, Opuscem, Opus PCF, Schottlander Ultra Fine Glass Composite, Quicktemp Cosmetic Flowable Composite, Matchmaker MC Metal Ceramic, Matchmaker HC, Matchmaker Zr Ceramic, Propaque Paste Opaque, enliven MC Metal Ceramic, enliven Paste Opaques, enliven Universal Stains, Matchmaker CTE Buffer, Starburst 45 Capsules.

The management system of Schottlander further conforms to:

ISO 13485:2016 Cert: GB97/9550

ISO 9001:2015 Cert: GB04/636198

Directive 93/42/EEC Cert: GB19/964610

Signature :

Brian Schottlander.

Position:

Managing Director

Date:

February 26th, 2020

Supersedes:

January 14th, 2020