

The management system of

**Davis Schottlander & Davis Ltd**

Fifth Avenue Letchworth Garden City, Herts SG6 2WD UK

AUTHORISED REP:

Schottlander (IRL) Ltd

Suite 11, Parklands Office Park, Southern Cross Road, Bray, Co. Wicklow, Eire

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 14<sup>th</sup> 1993, concerning medical devices (MDD), Annex V, as amended by EC Council Directive 2007/47/EC under the supervision of Notified Body number 1639, SGS Belgium NV, SGS House, Noorderlaan 87 2030, Antwerp, Belgium.

<b>Medical_Device_Name</b>	<b>GMDN_Code</b>	<b>Rule</b>
4natur Teeth	38643	Rule 8
Croform Excel S1 Alloy	35857	Rule 5
Delphic Tooth coloured Acrylic	63591	Rule 8
Enigma High Base Denture base	63591	Rule 5
Engima Teeth	38643	Rule 5
Enigmalive Teeth	38643	Rule5
enliven MC Porcelain	16187	Rule 8
enliven MC Porcelain Kit	44727	Rule 8
enliven Universal Stain Kit	44727	Rule 8
Matchmaker Kit	44727	Rule 8
Matchmaker MC Porcelain	16187	Rule 8
Matchmaker MC Powders	16187	Rule 8
Matchmaker ZR Porcelain	16187	Rule 8
Matchmate Alloy NP10	35857	Rule 8
Matchmate Alloy NP20	35857	Rule 8
Natura Teeth	38643	Rule 5
Opus PCF Polycarboxylate	16705	Rule 8
Opus Silver	16704	Rule 8
Opuscem GI Luting Cement	16704	Rule 8
Opusfil	16704	Rule 8
Pegasus Cold Cure Pourable Acrylic	63591	Rule 5
Pegasus Plus Denture Base	63591	Rule 5
Pegasus Plus Repair Acrylic	63591	Rule 5
Propaque Paste Opaque	16187	Rule 8

Quicktemp 2	45236	Rule 8
Quicktemp Cosmetic	45236	Rule 8
Quicktemp Cosmetic Flowable Composite	35870	Rule 8
Quicktemp Cosmetic Glaze and Bond	34771	Rule 5
Schottlander Ultrafine Glass Composite	35870	Rule 8
Starburst 45 Amalgam	16367	Rule 8

The management system of Schottlander further conforms to:

ISO 13485:2016	CERT: GB97/9550ISO
ISO 9001:2015	CERT: GB04/6319
DIRECTIVE 93/42/EEC	CERT GB19/964610
MDSAP ISO 13485:2016	GB20/965704

<b>Signature:</b>	<i>B D Schottlander</i> <small>B D Schottlander (Oct 6, 2021 17:56 GMT+1)</small>
<b>Print Name:</b>	Dr Brian Schottlander
<b>Position:</b>	Managing Director
<b>Date:</b>	6 <sup>th</sup> October 2021
<b>Supersedes:</b>	26 <sup>th</sup> February 2020


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Final Audit Report

2021-10-06

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