

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 I

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 VII, 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.

Medical device Name	GMDN Code	Rule
4natur Shade Guide	38651	Rule 1
Delphic and Delphic V Teeth	38643	Rule 5
Delphic Shade Guide O and G	38651	Rule 1
Delphic V Shade Guide	38651	Rule 1
Dental Rolls	31815	Rule 5
Doric Bite Extra Hard	35866	Rule 5
Doric Bite Hard	35866	Rule 5
Doric Definition High Definition Wash	35866	Rule 5
Doric Definition Super Soft Putty	35866	Rule 5
Doric Easy First Cartridge	35866	Rule 5
Doric Extra Heavy Fast	35866	Rule 5
Doric First	35866	Rule 5
Doric Flo-Light	35866	Rule 5
Doric Gingival Retraction Paste	61905	Rule 5
Doric Heavy	35866	Rule 5
Doric Light	35866	Rule 5
Doric Mixing Tips	58399	Rule 5
Doric Mono	35866	Rule 5
Doric Pink Toughened Wax	63983	Rule 5
Doric Pre-Cut Impression Separation Wafers	44575	Rule 5
Doric Quicktime Flo-Light	35866	Rule 5
Doric Quicktime Soft Putty	35866	Rule 5
Doric Reg Snap Set Putty	35866	Rule 5
Doric Regular Snap Set Putty	35866	Rule 5
Doric Soft Snap Set Putty	35866	Rule 5
Doric Universal Adhesive	16658	Rule 5
Enigma Shade Guide	38651	Rule 1
enigmalive Shade Guide	38651	Rule 1

Fidelity 25 Alginate Impression Material	35863	Rule 5
H C Stents	34807	Rule 5
Magilight Dry Coat sealant	34771	Rule 5
Magilight Tray Blanks	58106	Rule 5
Natura Shade Guide	38651	Rule 1
Quicktemp/Doric Gun	60885	Rule 5
Schottlander Mouthwash Tablets	42345	Rule 5
Schottlander Aloe Gloves Soft	47172	Rule 5
Schottlander Compule Applicator	16196	Rule 5
Schottlander Flexible Nitrile Examination Gloves	56286	Rule 5
Schottlander LA Low Allergy Powder Free Examination Gloves	47172	Rule 5
Schottlander Simply Soft Flexible Nitrile Examination Gloves	56286	Rule 5
Schottlander Soft Touch Flexible Nitrile Examination Gloves	56286	Rule 5
Schottlander Super Soft Flexible Nitrile Examination Gloves	56286	Rule 5
Schottlander Surgical Face Mask	35177	Rule 5

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>	 <small>B D Schottlander (Oct 6, 2021 15:52 GMT+1)</small>
<b>Name:</b>	Dr Brian Schottlander
<b>Position:</b>	Managing Director
<b>Date:</b>	6 <sup>th</sup> October 2021
<b>Supersedes:</b>	15 <sup>th</sup> January 2020

# Class I DoC 06.10.21

Final Audit Report

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