

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 14th, 1993, concerning medical devices (MDD), Annex VII, as amended by EC Council Directive 2007/47/EC.

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 Easy Heavy Cartridge	35866	Rule 5
Doric Easy Mono Cartridge	35866	Rule 5
Doric Easy Putty Cartridge	35866	Rule 5
Doric Extra Heavy Fast Setting	35866	Rule 5
Doric First	35866	Rule 5
Doric Flo-Light	35866	Rule 5
Doric Gingival Retraction Paste	47917	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 Regular Snap Set Putty	35866	Rule 5
Doric Soft Snap Set Putty	35866	Rule 5

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Doric Universal Adhesive	16658	Rule 5
Enigma Shade Guide	38651	Rule 1
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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	66199	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

Signature:	
Name:	Keith Dymond
Position:	QARA Manager
Date:	10 th May 2022
Supersedes:	1 st December 2021