

MEDICAL DEVICE REGULATION EC-DECLARATION OF CONFORMITY MDR CLASS I PRODUCTS

The management system of
Davis Schottlander & Davis Ltd
Fifth Avenue Letchworth Garden City, Herts SG6 2WD UK
SRN No: GB-MF-000035008

AUTHORISED REPRESENTATIVE:
Schottlander (IRL) Ltd
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SRN No: IE-AR-000029625

In accordance with Article 19 and Annex IV of Regulation (EU) 2017/745, it is hereby declared that the products listed below comply with all the applicable requirements of MDR (EU) 2017/745, having undergone the applicable conformity assessment procedure according to Article 52 of regulation (EU) 2017/745, as concerns class I medical devices.

The devices have been classified in accordance with the classification rules defined in annex VIII of MDR (EU) 2017/745, and the specific rule applicable to each device is provided in the table below.

Medical device Name	BASIC UDI	GMDN Code	Rule*
4natur Shade Guide	5052674TEETH-CL1AZ	38651	Rule 1
Delphic and Delphic V Teeth	5052674TEETH-CL1AZ	38643	Rule 5
Delphic Shade Guide O and G	5052674TEETH-CL1AZ	38651	Rule 1
Delphic V Shade Guide	5052674TEETH-CL1AZ	38651	Rule 1
Doric Bite Extra Hard	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Bite Hard	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Definition High Definition Wash	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Definition Super Soft Putty	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Easy First Cartridge	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Easy Heavy Cartridge	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Easy Mono Cartridge	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Easy Putty Cartridge	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Extra Heavy Fast Setting	5052674SILI-IMP-MAT92	35866	Rule 5
Doric First	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Flo-Light	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Gingival Retraction Paste	5052674GINGRETRPASTRK	47917	Rule 5
Doric Heavy	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Light	5052674SILI-IMP-MAT92	35866	Rule 5

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Doric Mixing Tips	5052674IMP-ACCSRR	58399	Rule 5
Doric Mono	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Quicktime Flo-Light	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Quicktime Soft Putty	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Regular Snap Set Putty	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Soft Snap Set Putty	5052674SILI-IMP-MAT92	35866	Rule 5
Doric Universal Adhesive	5052674IMP-MAT-ADHESKJ	16658	Rule 5
Enigma Shade Guide	5052674TEETH-CL1AZ	38651	Rule 1
enigmalive Shade Guide	5052674TEETH-CL1AZ	38651	Rule 1
Fidelity 25 Alginate Impression Material	5052674ALG-IMP-MATR4	35863	Rule 5
Magilight Dry Coat sealant	5052674DRY-COATXA	34771	Rule 5
Magilight Curing Special Trays	5052674IMP-TRAYF	58106	Rule 5
Quicktemp/Doric Gun	5052674IMP-ACCSRR	60885	Rule 5
Schottlander Compule Applicator	5052674IMP-ACCSRR	16196	Rule 5
Schottlander Flexible Nitrile Examination Gloves	5052674NIT-GLOVESVT	56286	Rule 5
Schottlander LA Low Allergy Powder Free Examination Gloves	5052674NRL-GLOVESXJ	47172	Rule 5
Schottlander Soft Touch Flexible Nitrile Examination Gloves	5052674NIT-GLOVESVT	56286	Rule 5
Schottlander Super Soft Flexible Nitrile Examination Gloves (0260)	5052674NIT-GLOVESVT	56286	Rule 5
Schottlander Surgical Face Mask	5052674FACEMASKSZN	66199	Rule 5

*Classification rule as per annex VIII of MDR (EU) 2017/745

The management system of Schottlander further conforms to:

Certificate	Issuing Notified Body	Certificate Number
ISO13485:2016	SGS Belgium NV	GB97/9550
ISO9001:2015	SGS Belgium NV	GB04/6319
DIRECTIVE 93/42/EEC	SGS Belgium NV	GB19/964610
MDSAP ISO 13485:2016	SGS Belgium NV	GB20/965704
UK MDR 2002	SGS United Kingdom Ltd	GB23/00000313

Signature:	<i>joe hagan-brown</i>
Signed on Behalf of:	Davis Schottlander & Davis Ltd
Print Name:	Joe Hagan-Brown
Position:	QARA Manager & Person Responsible for Regulatory Compliance

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Place of Issue	Fifth Avenue, Letchworth Garden City, Hertfordshire, SG62WD, UK
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