

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

|        |                                              |         |                    |             |            |             |            |
|--------|----------------------------------------------|---------|--------------------|-------------|------------|-------------|------------|
| Title: | <b>MDR Class I Declaration of conformity</b> | Doc Ref | EC DOC Class I MDR | Doc Rev no. | 21/09/2025 | Date Issued | 21/09/2025 |
|--------|----------------------------------------------|---------|--------------------|-------------|------------|-------------|------------|

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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 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      |

|                             |                                                                                     |
|-----------------------------|-------------------------------------------------------------------------------------|
| <b>Signature:</b>           |  |
| <b>Signed on Behalf of:</b> | Davis Schottlander & Davis Ltd                                                      |
| <b>Print Name:</b>          | Joe Hagan-Brown                                                                     |
| <b>Position:</b>            | QARA Manager & Person Responsible for Regulatory Compliance                         |
| <b>Place of Issue</b>       | Fifth Avenue, Letchworth Garden City, Hertfordshire, SG62WD, UK                     |

|        |                                              |         |                    |             |          |             |          |
|--------|----------------------------------------------|---------|--------------------|-------------|----------|-------------|----------|
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| <b>Date Issued:</b> | 21/09/2025               |
| <b>Supersedes:</b>  | 02/09/2024<br>31/01/2024 |

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