# *EU MDR Declaration of Conformity*

*This declaration is issued under the sole responsibility of the manufacturer*
*Stafford-Miller (Ireland) Limited*

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| **Identification of the Legal Manufacturer:** | Stafford-Miller (Ireland) Limited,<br>Clocherane,<br>Youghal Road,<br>Dungarvan,<br>Co.Waterford,<br>X35 Y983,<br>Ireland |
| **This Declaration of Conformity is issued under the sole responsibility of the Stafford-Miller (Ireland) Limited** | |
| **Basic Unique Device Identifier - Device Identifier (UDI-DI):** | 50596230DP000000000H838U |
| **SRN #** | SRN No. IE-MF-000002788 |
| **Device Classification:** | EU Medical Device Class IIa |
| **Identification of the device(s) concerned:** | See table below |
| **Trade Names:** | As above |
| **Intended Purpose of Device:** | Improved denture hold |
| **Risk Classification and Classification Rule:** | Denture Adhesive Creams have been classified as a Class IIa Medical Device according to Rule 21.<br>Rule 21<br>All devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:<br><br>- class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx and achieve their intended purpose on those cavities. |

| **Product Description** | **Formulation** |
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| Poligrip/Corega/Polident Original Denture Adhesive Cream | IB0754/MFC50884 |
| Poligrip/Corega/Polident Free Denture Adhesive Cream | IB1183/MFC50819 |
| Poligrip/Corega/Polident Denture Adhesive Cream | MFC50880/MFC50885 |
| Poligrip/Corega/Polident Ultra Fresh Denture Adhesive Cream | MFC50882/MFC50887 |
| Poligrip/Corega/Polident Extra Care Denture Adhesive Cream | MFC50814/MFC50930 |
| Poligrip/Corega/Polident Low Gantrez Denture Adhesive Cream | MFC50937 |
| Poligrip/Corega/Polident Hold and Comfort | MFC05612 |
| Poligrip/Corega/Polident Hold and Seal | MFC05621 |
| Poligrip/Corega/Polident Hold and Seal Mint | MFC05622 |
| Poligrip/Corega/Polident Hold and Fresh | MFC05600 |



**We hereby declare that the above-mentioned devices comply with the general safety and performance requirements (GSPR) as laid down in Annex I of the regulation EU 2017/745 (MDR) and with the other applicable Union Legislations that require issuing a Declaration of Conformity as stated below.**

**The required technical documentation has been prepared and is available to the national authorities for inspection purposes.**

**This declaration is issued in accordance with Article 19 and Annex IV of Regulation 2017/745**

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| **European Directives and Regulations** | Medical Device Regulation 2017/745 |
| **Name, address and identification number of Notified Body:** | SGS Belgium NV,<br>SGS House Noorderlaan 87 2030<br>Antwerp Belgium<br>Notified Body number: 1639 |
| **Conformity Assessment Route:** | MDR EU Quality Management System Certificate (Annex IX QMS) |
| **Applicable CE Certificate and associated Annex:** | CE Certificate No: GB23/00000413<br>ISO 13485 Certificate No: GB21/968492 |

**Approved by:**

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| Regulatory Affairs Director Oral Health/Designate | Reference electronic signature applied |
| Person Responsible for Regulatory Compliance/designate | Reference electronic signature applied |

EU MDR Denture Adhesive Cream Declaration of Conformity

Document Approvals by Electronic Signature

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|---|---|
| Verdict: Approve | Stuart Elliott se573348<br>(stuart.x.elliott@haleon.com)<br>Regulatory Approval<br>10-Jan-2024 10:29:36 GMT+0000 |

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| Verdict: Approve | Danielle Egan dmm81751<br>(danielle.m.egan@haleon.com)<br>Author Approval<br>10-Jan-2024 10:36:53 GMT+0000 |

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| Verdict: Approve | Cora Cooney cac52902<br>(Cora.A.Cooney@haleon.com)<br>Quality Assurance Approval<br>12-Jan-2024 14:05:48 GMT+0000 |