EU MDR Declaration of Conformity

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

Identification of the Legal Manufacturer:	Stafford-Miller (Ireland) Limited, Clocherane, Youghal Road, Dungarvan, Co.Waterford, X35 Y983, 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):	50596230DP000000000H9593
SRN #	SRN No. IE-MF-000002788
Device Classification:	EU Medical Device Class IIb
Identification of the device(s) concerned:	**Product Description*** / **Formulation** Polident/Corega Bioformula / MFC05313 Quick Cleaning Polident/Corega with Enzyme / MFC05314 Quick Cleaning Polident/Corega with Triple Mint / MFC05315 Polident/Corega Overnight; Polident/Corega Whitening / MFC05316 Polident/Corega Antibacterial; Polident/Corega Pro-Guard and Retainer / MFC05318 Polident/Corega Double Power; Polident/Corega Complete Protection/Max Clean / MFC05322
Trade Names:	***Each product shall be identified by the formulation number. The variant names are only indicative, and they may vary across markets.
Intended Purpose of Device:	For use with removable dental appliances (Dentures, Retainers, Aligners, Nightguards)
Risk Classification and Classification Rule:	Cleansing tablets have been classified as a Class IIb Medical Device according to Rule 16. Denture cleansing tablets are Non- invasive device, intended specifically to be used for disinfecting other invasive devices (Dentures). As described in the classification table below, the applicable rules of Annex VIII of Regulation (EU) 2017/745 are Rule 1 and Rule 16

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

Approved

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European Directives and Regulations	Medical Device Regulation 2017/745
Name, address and identification number of Notified Body:	SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium 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 ISO 13485 Certificate No: GB21/968492

Approved by:

Regulatory Affairs Director Oral Health/Designate	Stuart Elliott
Person Responsible for Regulatory Compliance/designate	Cathy Cunningham

Approved

EU MDR Cleansing Tablets Declaration of Conformity
Document Approvals by Electronic Signature

Verdict: Approve	Danielle Egan dmm81751 (danielle.m.egan@haleon.com) Author Approval 14-May-2024 12:03:33 GMT+0000

Verdict: Approve	Cathy Cunningham cfw60729 (cathy.x.cunningham@haleon.com) Quality Risk & Compliance Approval 14-May-2024 12:57:03 GMT+0000

Verdict: Approve	Stuart Elliott se573348 (stuart.x.elliott@haleon.com) Regulatory Approval 15-May-2024 08:15:41 GMT+0000

Approved