


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																						
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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:	<table border="1"> <thead> <tr> <th data-bbox="750 683 1109 716">Product Description*</th> <th data-bbox="1109 683 1460 716">Formulation</th> </tr> </thead> <tbody> <tr> <td data-bbox="750 716 1109 750">Polident/Corega Bioformula</td> <td data-bbox="1109 716 1460 750">MFC05313</td> </tr> <tr> <td data-bbox="750 750 1109 806">Quick Cleaning Polident/Corega with Enzyme</td> <td data-bbox="1109 750 1460 806">MFC05314</td> </tr> <tr> <td data-bbox="750 806 1109 862">Quick Cleaning Polident/Corega with Triple Mint</td> <td data-bbox="1109 806 1460 862">MFC05315</td> </tr> <tr> <td data-bbox="750 862 1109 918">Polident/Corega Overnight; Polident/Corega Whitening</td> <td data-bbox="1109 862 1460 918">MFC05316</td> </tr> <tr> <td data-bbox="750 918 1109 996">Polident/Corega Antibacterial; Polident/Corega Pro-Guard and Retainer</td> <td data-bbox="1109 918 1460 996">MFC05318</td> </tr> <tr> <td data-bbox="750 996 1109 1086">Polident/Corega Double Power; Polident/Corega Complete Protection</td> <td data-bbox="1109 996 1460 1086">MFC05322</td> </tr> <tr> <td data-bbox="750 1086 1109 1142">Polident Active Bubbles Smokers / Overnight Whitening</td> <td data-bbox="1109 1086 1460 1142">MFC06161</td> </tr> <tr> <td data-bbox="750 1142 1109 1176">Polident Active Bubbles 3-minute</td> <td data-bbox="1109 1142 1460 1176">MFC06162</td> </tr> <tr> <td data-bbox="750 1176 1109 1232">Polident Active Bubbles Partial / Ortho Enzyme</td> <td data-bbox="1109 1176 1460 1232">MFC06166</td> </tr> <tr> <td data-bbox="750 1232 1109 1288">Polident Active Bubbles Max Clean / Double Power</td> <td data-bbox="1109 1232 1460 1288">MFC06155</td> </tr> </tbody> </table>	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	MFC05322	Polident Active Bubbles Smokers / Overnight Whitening	MFC06161	Polident Active Bubbles 3-minute	MFC06162	Polident Active Bubbles Partial / Ortho Enzyme	MFC06166	Polident Active Bubbles Max Clean / Double Power	MFC06155
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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:	<p>Cleansing tablets have been classified as a Class IIb Medical Device according to Rule 16.</p> <p>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</p>																						
<p>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.</p> <p>The required technical documentation has been prepared and is available to the national authorities for inspection purposes.</p> <p>This declaration is issued in accordance with Article 19 and Annex IV of Regulation 2017/745</p>																							

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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 Regulatory Affairs – Gum, Denture and Family	Sarah Landra
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 30-Jan-2025 10:33:56 GMT+0000
Verdict: Approve	Sarah Landra sl912524 (sarah.x.landra@haleon.com) Regulatory Approval 31-Jan-2025 10:01:24 GMT+0000
Verdict: Approve	Cathy Cunningham cfw60729 (cathy.x.cunningham@haleon.com) Quality Risk & Compliance Approval 31-Jan-2025 11:21:40 GMT+0000

APPROVED