EU Quality Management System Certificate GB23/00000413

The management system of

Stafford Miller (Ireland) Ltd.

Clocherane Youghal Road Dungarvan Co Waterford X35 Y983 Republic of Ireland
SRN Number: IE-MF-000002788

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

Class IIa MDN 1209 MDS1008
Denture Adhesive Creams (B-UDI: 50596230DP000000000H838U)
Denture Adhesive Powders (B-UDI: 50596230DP000000000H858Y)

Class IIb MDN 1211 Cleansing tablets for use with removable dental appliances (Dentures, Retainers, Aligners, Nightguards) (B-UDI: 50596230DP000000000H9593)

Intended use: The Polident/Corega/Poligrip Denture Cleansing Tablets are intended to remove food particles, stains, germs, and plaque from removable prosthetic dental appliances such as partial and full dentures by action outside the body

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: GB/PC/225650 - CTC 1.25
Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A
Change in between this certificate and previous one: Missing B-UDI (50596230DP000000000H858Y) for the Class II-a Denture Adhesive Powders was added into the scope.

This certificate is valid from 21 December 2023 until 08 December 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 08 June 2028

Issue 2. Certified since 08 December 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
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Stafford-Miller (Ireland) Limited MDR CE Certificate
Document Approvals by Electronic Signature

Verdict: Approve	Danielle Egan dmm81751 (danielle.m.egan@haleon.com) Author Approval 08-Jan-2024 15:09:33 GMT+0000

Verdict: Approve	Cora Cooney cac52902 (Cora.A.Cooney@haleon.com) Quality Assurance Approval 08-Jan-2024 16:47:48 GMT+0000