HALEON

EU MDD Declaration of Conformity

Governing SOP:
QD-SOP-009864 Compliance to MDD, MDR UK and the Route to CE Marking and UKCA Marking.

EU MDD Declaration of Conformity

Completed by Manufacturer:

Identification of the Legal Manufacturer:	Haleon Medical Devices Clocherane, Youghal Road, Dungarvan Co.Waterford, X35 Y983 Ireland
This Declaration of Conformity is issued under the sole responsibility of Haleon Medical Devices	
Identification of the device(s) concerned:	Product Description: Polident/Corega Denture Cleanser Foam Formulation: MFC51023
Trade Names:	Polident Fresh Cleanser Foam (Denture Cleanser/Breath Freshener) Polident/Corega ProPartial Foam Cleanser
Intended Purpose of Device:	Denture Cleanser Foam is intended to remove food particles, stains, plaque and kill bacteria from removable prosthetic dental appliances such as dentures or partial dentures by action outside of the body with the aid of a brush
Device Classification :	Class IIb, Rule 15
Applicable CE Certificate and associated Annex :	EC Quality Certificate Annex II No. GB19/963038 (Denture Cleansers) issued by SGS Belgium NV, Notified Body No.1639 and Quality System Approval Certificate GB21/969218
Notified Body Name and Number:	**SGS Belgium NV,** SGS House Noorderlaan 87 2020 Antwerp Belgium **Notified Body number: 1639**
Batch Number:	All lots released from/All lots manufactured from Nov 2023 until such time as significant changes are made to product, its starting materials or key subcontractors.
Name and Address of Manufacturing Site and applicable formulations	Manufacturing Site Name and Address: Accupac, LLC 1501 Industrial Blvd. Mainland PA 19451 USA Formulations Manufactured: MFC51023

We, the undersigned, hereby declare that the medical device specified above conforms to the Essential Requirements listed in Annex I of Council Directive 93/42/EEC (as amended by directive 2007/47/EC).

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

This declaration is carried under Annex VII of Directive 93/42/EEC (as amended by 2007/47/EC).

Document revision history

REVISION **(Principal Changes from last revision)**
Type of change: ☐ New ☐ Revision with minor changes; ☒ Revision with major changes impacting: ☒ Roles and responsibilities ☐ process or activities **Reason for Change**: 1. Legal Manufacturer entity name change, ref: change control QE-090433 **Description of Change** 1. Identification of the Legal Manufacturer section, - updated Medical Device Legal Manufacturer details to: Haleon Medical Devices Clocherane, Youghal Road, Dungarvan Co.Waterford, X35 Y983 Ireland

MDD DOC Denture Cleanser Foam

Document Approvals by Electronic Signature

Verdict: Approve	Sanjiv Vij sv732555 (sanjiv.x.vij@haleon.com) Author Approval 13-Nov-2023 09:52:49 GMT+0000

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