


**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:

<b>Identification of the Legal Manufacturer:</b>	 Haleon Medical Devices Clocherane, Youghal Road, Dungarvan Co. Waterford, X35 Y983 Ireland					
<b>This Declaration of Conformity is issued under the sole responsibility of Haleon Medical Devices</b>						
<b>Identification of the device(s) concerned:</b>	<table border="1"> <thead> <tr> <th data-bbox="740 815 1034 875">Product Description</th> <th data-bbox="1034 815 1291 875">Formulation</th> </tr> </thead> <tbody> <tr> <td data-bbox="740 875 1034 972">Polident/Corega Denture Cleanser Foam</td> <td data-bbox="1034 875 1291 972">MFC51023</td> </tr> </tbody> </table>	Product Description	Formulation	Polident/Corega Denture Cleanser Foam	MFC51023	
Product Description	Formulation					
Polident/Corega Denture Cleanser Foam	MFC51023					
<b>Trade Names:</b>	Polident Fresh Cleanser Foam (Denture Cleanser/Breath Freshener) Polident/Corega ProPartial Foam Cleanser					
<b>Intended Purpose of Device:</b>	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					
<b>Device Classification :</b>	Class IIb, Rule 15					
<b>Applicable CE Certificate and associated Annex :</b>	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					
<b>Notified Body Name and Number:</b>	<b>SGS Belgium NV,</b> SGS House Noorderlaan 87 2020 Antwerp Belgium  <b>Notified Body number: 1639</b>					
<b>Batch Number:</b>	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.					
<b>Name and Address of Manufacturing Site and applicable formulations</b>	<table border="1"> <thead> <tr> <th data-bbox="740 1680 1157 1771">Manufacturing Site Name and Address</th> <th data-bbox="1157 1680 1481 1771">Formulations Manufactured</th> </tr> </thead> <tbody> <tr> <td data-bbox="740 1771 1157 1964">           Accupac, LLC            1501 Industrial Blvd.            Mainland PA 19451            USA         </td> <td data-bbox="1157 1771 1481 1964">           MFC51023         </td> </tr> </tbody> </table>	Manufacturing Site Name and Address	Formulations Manufactured	Accupac, LLC 1501 Industrial Blvd. Mainland PA 19451 USA	MFC51023	
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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

<b>REVISION</b> <b>(Principal Changes from last revision)</b>
Type of change: <input type="checkbox"/> New <input type="checkbox"/> Revision with minor changes; <input checked="" type="checkbox"/> Revision with major changes impacting: <input checked="" type="checkbox"/> Roles and responsibilities <input type="checkbox"/> process or activities
<b>Reason for Change:</b> 1. Legal Manufacturer entity name change, ref: change control QE-090433
<b>Description of Change</b> 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
Verdict: Approve	Tara Roche tsr15383 (tara.x.roche@haleon.com) Quality Assurance Approval 13-Nov-2023 17:02:16 GMT+0000
Verdict: Approve	Stuart Elliott se573348 (stuart.x.elliott@haleon.com) Regulatory Approval 14-Nov-2023 11:40:03 GMT+0000

APPROVED