

EU MDR Declaration of Conformity

Governing SOP: QD-SOP-009503 / Compliance to MDR & Route to CE Marking

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.																														
Basic Unique Device Identifier - Device Identifier (UDI-DI):	50596230DP000000000M359A																													
SRN #	IE-MF-000002458																													
Identification of the device(s) concerned:	Medical Device Description: Parodontax/Corsodyl Sodium bicarbonate dentifrice for stopping/preventing bleeding gums by removal of plaque. <table border="1" data-bbox="606 772 1500 1235"> <thead> <tr> <th>Product description</th> <th>Formulation</th> </tr> </thead> <tbody> <tr><td>parodontax/Corsodyl Daily Fluoride</td><td>MFC05694</td></tr> <tr><td>parodontax/Corsodyl Original (Classic) Fluoride-Free</td><td>MFC04212</td></tr> <tr><td>parodontax/Corsodyl Extra Fresh Toothpaste</td><td>MFC05692</td></tr> <tr><td>parodontax/Corsodyl Whitening Toothpaste</td><td>MFC05693</td></tr> <tr><td>parodontax/Corsodyl Ultra Clean Toothpaste</td><td>MFC05687</td></tr> <tr><td>parodontax/Corsodyl Complete Protection Whitening Toothpaste</td><td>MFC05688</td></tr> <tr><td>parodontax/Corsodyl Complete Protection Extra Fresh Toothpaste</td><td>MFC05689</td></tr> <tr><td>parodontax/Corsodyl Herbal Fresh Toothpaste</td><td>MFC05732</td></tr> <tr><td>parodontax/Corsodyl Herbal Sensation Toothpaste</td><td>MFC05733</td></tr> <tr><td>parodontax Active Gum Repair Fresh Mint Toothpaste</td><td>MFC05831</td></tr> <tr><td>parodontax Active Gum Repair Whitening Toothpaste</td><td>MFC05832</td></tr> <tr><td>parodontax/Corsodyl Intensive Gum Repair Intense Clean Toothpaste</td><td>MFC06082</td></tr> <tr><td>parodontax/Corsodyl Intensive Gum Repair White & Polish Toothpaste</td><td>MFC06080</td></tr> </tbody> </table>		Product description	Formulation	parodontax/Corsodyl Daily Fluoride	MFC05694	parodontax/Corsodyl Original (Classic) Fluoride-Free	MFC04212	parodontax/Corsodyl Extra Fresh Toothpaste	MFC05692	parodontax/Corsodyl Whitening Toothpaste	MFC05693	parodontax/Corsodyl Ultra Clean Toothpaste	MFC05687	parodontax/Corsodyl Complete Protection Whitening Toothpaste	MFC05688	parodontax/Corsodyl Complete Protection Extra Fresh Toothpaste	MFC05689	parodontax/Corsodyl Herbal Fresh Toothpaste	MFC05732	parodontax/Corsodyl Herbal Sensation Toothpaste	MFC05733	parodontax Active Gum Repair Fresh Mint Toothpaste	MFC05831	parodontax Active Gum Repair Whitening Toothpaste	MFC05832	parodontax/Corsodyl Intensive Gum Repair Intense Clean Toothpaste	MFC06082	parodontax/Corsodyl Intensive Gum Repair White & Polish Toothpaste	MFC06080
Product description	Formulation																													
parodontax/Corsodyl Daily Fluoride	MFC05694																													
parodontax/Corsodyl Original (Classic) Fluoride-Free	MFC04212																													
parodontax/Corsodyl Extra Fresh Toothpaste	MFC05692																													
parodontax/Corsodyl Whitening Toothpaste	MFC05693																													
parodontax/Corsodyl Ultra Clean Toothpaste	MFC05687																													
parodontax/Corsodyl Complete Protection Whitening Toothpaste	MFC05688																													
parodontax/Corsodyl Complete Protection Extra Fresh Toothpaste	MFC05689																													
parodontax/Corsodyl Herbal Fresh Toothpaste	MFC05732																													
parodontax/Corsodyl Herbal Sensation Toothpaste	MFC05733																													
parodontax Active Gum Repair Fresh Mint Toothpaste	MFC05831																													
parodontax Active Gum Repair Whitening Toothpaste	MFC05832																													
parodontax/Corsodyl Intensive Gum Repair Intense Clean Toothpaste	MFC06082																													
parodontax/Corsodyl Intensive Gum Repair White & Polish Toothpaste	MFC06080																													
Trade Names/Product Code:	<table border="1" data-bbox="606 1215 1500 1961"> <tbody> <tr> <td>parodontax Fluoride/ Pasta zubná parodontax Fluoride (100 ml, 75 ml, 2 x 75 ml)</td> <td>MFC05694</td> </tr> <tr> <td>parodontax Classic/ Pasta zubná parodontax Classic (75 ml)</td> <td>MFC04212</td> </tr> <tr> <td>parodontax Extra Fresh/ Pasta zubná parodontax Extra Fresh (75 ml)</td> <td>MFC05692</td> </tr> <tr> <td>parodontax Whitening/ Pasta zubná parodontax Whitening (100 ml, 75 ml, 2 x 75 ml)</td> <td>MFC05693</td> </tr> <tr> <td>parodontax Ultra Clean/ Pasta zubná parodontax Ultra Clean (100 ml, 75 ml)</td> <td>MFC05687</td> </tr> <tr> <td>Parodontax Kompletní ochrana Whitening/ Pasta zubná parodontax Kompletná ochrana Whitening (75 ml)</td> <td>MFC05688</td> </tr> <tr> <td>parodontax Kompletní ochrana Extra Fresh/ Pasta zubná parodontax Kompletná ochrana Extra Fresh (75 ml)</td> <td>MFC05689</td> </tr> </tbody> </table>		parodontax Fluoride/ Pasta zubná parodontax Fluoride (100 ml, 75 ml, 2 x 75 ml)	MFC05694	parodontax Classic/ Pasta zubná parodontax Classic (75 ml)	MFC04212	parodontax Extra Fresh/ Pasta zubná parodontax Extra Fresh (75 ml)	MFC05692	parodontax Whitening/ Pasta zubná parodontax Whitening (100 ml, 75 ml, 2 x 75 ml)	MFC05693	parodontax Ultra Clean/ Pasta zubná parodontax Ultra Clean (100 ml, 75 ml)	MFC05687	Parodontax Kompletní ochrana Whitening/ Pasta zubná parodontax Kompletná ochrana Whitening (75 ml)	MFC05688	parodontax Kompletní ochrana Extra Fresh/ Pasta zubná parodontax Kompletná ochrana Extra Fresh (75 ml)	MFC05689														
parodontax Fluoride/ Pasta zubná parodontax Fluoride (100 ml, 75 ml, 2 x 75 ml)	MFC05694																													
parodontax Classic/ Pasta zubná parodontax Classic (75 ml)	MFC04212																													
parodontax Extra Fresh/ Pasta zubná parodontax Extra Fresh (75 ml)	MFC05692																													
parodontax Whitening/ Pasta zubná parodontax Whitening (100 ml, 75 ml, 2 x 75 ml)	MFC05693																													
parodontax Ultra Clean/ Pasta zubná parodontax Ultra Clean (100 ml, 75 ml)	MFC05687																													
Parodontax Kompletní ochrana Whitening/ Pasta zubná parodontax Kompletná ochrana Whitening (75 ml)	MFC05688																													
parodontax Kompletní ochrana Extra Fresh/ Pasta zubná parodontax Kompletná ochrana Extra Fresh (75 ml)	MFC05689																													

EU MDR Declaration of Conformity

Governing SOP: QD-SOP-009503 / Compliance to MDR & Route to CE Marking

	parodontax Herbal Fresh/ Pasta zubná parodontax Herbal Fresh (75 ml)	MFC05732
	parodontax Kompletní ochrana Herbal Sensation/ Pasta zubná parodontax Kompletná ochrana Herbal Sensation (75 ml)	MFC05733
	parodontax Aktivní obnova dásní Fresh Mint/ Pasta zubná parodontax Aktivna obnova d'asien Fresh Mint (75 ml, 15 ml)	MFC05831
	parodontax Aktivní obnova dásní Whitening/ Pasta zubná parodontax Aktivna obnova d'asien Whitening (75 ml)	MFC05832
	parodontax Intensive Gum Repair Intense Clean (75 ml, 15 ml)	MFC06082
	parodontax Intensive Gum Repair White & Polish (75 ml)	MFC06080
Intended Purpose of Device and Intended Users:	Dentifrice for the treatment and prevention of gingivitis/early gum disease through the physical removal of dental plaque.	
	The intended use of “gum disease treatment” may be covered in other appropriate language that is more meaningful to user, for example, bleeding gums, red & inflamed gums.	
Risk Classification and Classification Rule:	The Sodium Bicarbonate Dentifrice is intended to be used by lay persons: adults and adolescents (12 years and above) to treat and prevent gingivitis/early gum disease.	
	Class IIa Rule 21	
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 under Article 19 and Annex IV of Regulation 2017/745		
European Directives and Regulations	Medical Device Regulation 2017/745	
Common specifications (If applicable)	Not applicable	
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:	Annex IX – Quality System & Technical Documentation according to MDR 2017/745	
Applicable CE Certificate and associated Annex:	EC Quality Certificate Annex IX No. GB25/00000188 (Parodontax/Corsodyl sodium bicarbonate dentifrice for stopping/preventing bleeding gums by removal of plaque) issued by SGS Belgium NV, Notified Body No. 1639 and Quality System Approval Certificate GB21/969218.	
Date of Issue:	Date of issue as per approved date present on document header of effective document.	

EU MDR Declaration of Conformity

Governing SOP: QD-SOP-009503 / Compliance to MDR & Route to CE Marking

Name and Address of Manufacturing Site and applicable formulations	Manufacturing Site Name and Address	Formulations Manufactured
	Haleon Levice, s.r.o Priemyselný park GEŇA, Ul. E. Sachsa 4-6, 934 01 Levice, Republic of Slovakia.	MFC04212, MFC05732, MFC05733, MFC05687, MFC05688, MFC05689, MFC05690, MFC05691, MFC05692, MFC05693, MFC05694, MFC05831, MFC05832, MFC06080, MFC06082

Approved by: _____

Margaret O'Sullivan

Date: _____

07/01/2026

Margaret O'Sullivan
Compliance Manager
Haleon Medical Devices

Haleon Medical Devices
Clocherate
Youghal Road
Dungarvan
Co. Waterford
X35 Y983
Ireland