


EC Declaration of Conformity



Manufacturer:	Procter & Gamble Technical Centres Limited, The Heights, Brooklands, Weybridge, Surrey, KT13 0XP, United Kingdom SRN: GB-MF-000017862	
Authorised Representative	Procter & Gamble Service GmbH Sulzbacher Str. 40 65824 Schwalbach a. Ts. Germany SRN: DE-AR-000016615	
Product name:	Denture Adhesive	
European Medical Devices Nomenclature (CND):	Q010280 - Devices For Prosthetic Dentistry - Accessories	
Trade (brand) name:	<ul style="list-style-type: none"> • Blend-a-dent • Fixodent • Kukident 	
Product reference:	Formula Card:	Basic UDI-DI:
	<ul style="list-style-type: none"> • GCAS 91708115 • GCAS 91747026 • GCAS 91765544 • GCAS 91765549 • GCAS 91686380 • GCAS 91747031 • GCAS 91747032 • GCAS 91708133 • GCAS 90373008 	<ul style="list-style-type: none"> • 8001090dentadhZF
Intended Purpose:	The primary intended use of the denture adhesive is to improve the performance of custom-made removable dental prosthetic devices (dentures) by aiding their retention and stability in the oral cavity.	
Class:	IIa	
Notified body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany	
Notified body registration number:	0197	
Certificate Issue	HZ-1200911-1	
Common Specifications:	Not Applicable	

We hereby declare that the above mentioned medical device family comply with all the provisions of Regulation (EU) 2017/745 which apply, and accordingly, the  mark with Notified Body registration number 0197 will be placed on all production batches placed on the market in the member states of the European Union and EFTA as defined in this declaration under Annex IX - Chapters I and III and including an assessment of the technical documentation as specified in Section 4. This Declaration of Conformity is only valid in connection with the release documents for the respective batch of produced devices. All supporting documentation is retained by the manufacturer. The declaration of conformity is issued under the sole responsibility of the manufacturer.

Weybridge
Place

25-Sep-2023
Date

Maneesh Nerurkar
Maneesh Nerurkar (Sep 25, 2023 09:30 GMT+1)
Signature

Maneesh Nerurkar
Top Management, Medical Devices
On behalf of
Procter & Gamble Technical Centres Ltd.








09_01 Attachment 1a DoC MDR Weybridge DA vSep-2023

Final Audit Report

2023-09-25

Created:	2023-09-25
By:	sadek.es@pg.com
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"09_01 Attachment 1a DoC MDR Weybridge DA vSep-2023" History

-  Document created by sadek.es@pg.com
2023-09-25 - 7:30:00 AM GMT
-  Document emailed to nerurkar.m@pg.com for signature
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-  Email viewed by nerurkar.m@pg.com
2023-09-25 - 8:29:44 AM GMT
-  Signer nerurkar.m@pg.com entered name at signing as Maneesh Nerurkar
2023-09-25 - 8:30:16 AM GMT
-  Maneesh Nerurkar (nerurkar.m@pg.com) has agreed to the terms of use and to do business electronically with Procter & Gamble
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-  Document e-signed by Maneesh Nerurkar (nerurkar.m@pg.com)
Signature Date: 2023-09-25 - 8:30:18 AM GMT - Time Source: server
-  Agreement completed.
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