



GAP Research Co. Ltd.

Manufacturers of Dental Care Products



EC DECLARATION OF CONFORMITY

Manufacturer: GAP Research Co Ltd
Address: Unit 2 Ebbsfleet Business Park, Stonebridge Road, Gravesend, Kent, DA11 9DZ England
Basic UDI – DI: 5031966GAP101FY
Single Registration Number: TBA

EU Authorised Representative:

Name: Denvtech Ltd.,
Address: Ground floor, 8-9 Marino Mart, Fairview, Clontarf, Dublin 3, DO3 P590
Single Registration Number: XI-AR-000034984

List of devices and classification according to Annex IX class I

Product	GMDN	Intended purpose	UDI number
Dr Denti Refit	61482	Temporary cement	5031966009122
Dr Denti Sof Grip	31788	Temporary denture liner	5031966033899
Dr Denti Super Fix	31787	Denture repair	5031966000051
Dr Denti Smile	11168	Dentrifices	5031966035633
Dr Denti Toothpaste Tablets	11168	Dentrifices	5031966000129
Dr Denti Water Flosser Tablets	42345	Oral Cleanser	5031966000143
MGS Mouthwash Tablets	42345	Oral cleanser	5031966551126
MGS Disclosing Tablets	42345	Plaque discloser	5031966000105
MGS Propy Paste	11168	Dentrifices	5031966501619
MGS Fun Mouthwash	42345	Oral Cleanser	5031966021117

This declaration of conformity is created according to annex IV of Regulation (EU) 2017/745 (MDR), and UK Medical Device Regulation 2002-SI 618 as amended. The device of declaration described above has been classified as a Class I medical device in accordance with MDR annex VIII rule 5 (first indent) and the manufacturer has therefore followed the self declaration conformity assessment route described in article 52(7) of this community harmonised legislation.

The manufacturer declares conformance to all general safety and performance requirements laid down in annex I of MDR by reference to the following international standards: EN ISO 1479:2019, EN ISO 10993-1:2020 and EN ISO 15223-1:2016, as well as all applicable implementing regulations, interpretations and guidance. The methods adopted by the manufacturer to meet these requirements have been appropriately documented in technical documentation that is conformance with annex II and III of MDR.

This declaration is issued under the sole responsibility of the manufacturer detailed above.

Signed for and on behalf of GAP Research Co. Ltd. at the address listed above:

Name: Mr A S Photay
Role: Technical Director
Issue date: 31st May 2023
Expiry date: 31st May 2028

MDD 1 Dec of Conf

31st May 2023

Issue 9

Tech Dir

ASP



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