



Document Detail

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Title: Visco-gel Declaration of Conformity
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Status: CURRENT
Effective Date: 02-Nov-2023

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	02-Nov-2023 3:13 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	02-Nov-2023 6:23 pm	GMT

**VISCO-GEL TEMPORARY SOFT DENTURE LINER
DoC - DECLARATION OF CONFORMITY**

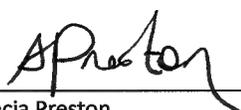


CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
Authorized EU-representative:	Dentsply DeTrey GmbH De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	NAME
616.05.002	Visco-gel Temporary Soft Denture Liner Package
Classification and Rules (EU and UK)	EU class: Class I following Rule 5, transient, invasive device ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: N/A ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI	++D002RELINERTISSUECONDQG
EMDN code / description	Q010299 - Prosthetic Dentistry Devices - Others
GMDN code / description	17610 - Denture reliner, soft, professional
Intended purpose	Visco-gel Temporary Soft Denture Liner is used as a Tissue Conditioner and temporary reliner when denture-bearing soft tissues have been distorted by trauma or infection, as a functional impression material when a complete denture is to be rebased or remade, and as a soft liner, especially for aged patients or patients with impaired tissue health.
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF</p> <ul style="list-style-type: none"> - THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES II AND III. - THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478). <p>ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>	
External references (Common Specifications, Standards, Regulations) applied	TF057-LAER
EC Certificate	N/A
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF057

Dentsply LLC, also trading as
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38 West Clarke Avenue
Milford DE 19963
USA



Stacia Preston
Regulatory Compliance Manager

11/1/23

Date

FORM NO	8000-FM-008-05	REVISION LEVEL	6
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