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Approval

Owner Role	Sign-off By	Sign-off Date	
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

Dentsply Sirona

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.
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF - 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). ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
External references (Common Specifications, Standards, Regulations) applied	TF057-LAER
EC Certificate	N/A
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF057

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APreston 11/1/23

Stacia Preston — Date
Regulatory Compliance Manager