

Document Detail

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Title: Palodent V3 Sectional Matrix System Declaration of Conformity
Comment:
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

PALODENT® V3 SECTIONAL MATRIX SYSTEM DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
RECORD NUMBER	MILFORD 0070-TF024-DOC-11	REVISION LEVEL	7	PAGE NO	Page 1 of 2

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
659700v	Palodent® V3 Sectional Matrix System Introductory Kit
659710v	Palodent® V3 Sectional Matrix System 3.5mm Matrices Refill
659720v	Palodent® V3 Sectional Matrix System 4.5mm Matrices Refill
659730v	Palodent® V3 Sectional Matrix System 5.5mm Matrices Refill
659740v	Palodent® V3 Sectional Matrix System 5.5mm Matrices Refill (100ct)
659750v	Palodent® V3 Sectional Matrix System 6.5mm Matrices Refill
659760v	Palodent® V3 Sectional Matrix System Universal Rings Refill
659770v	Palodent® V3 Sectional Matrix System Narrow Rings Refill
659780v	Palodent® V3 Sectional Matrix System Small Wedges Refill
659790v	Palodent® V3 Sectional Matrix System Medium Wedges Refill
659800v	Palodent® V3 Sectional Matrix System Large Wedges Refill
659810v	Palodent® V3 Sectional Matrix System Forceps
659820v	Palodent® V3 Sectional Matrix System Pin Tweezers
659830v	Palodent® V3 Sectional Matrix System Small Wedge Guard Refill
659840v	Palodent® V3 Sectional Matrix System Medium Wedge Guard Refill
659850v	Palodent® V3 Sectional Matrix System Large Wedge Guard Refill
659860v	Palodent® V3 Sectional Matrix System 7.5mm Matrices Refill
659900v	Palodent® V3 Sectional Matrix System Ring Refill
625.00.005	Palodent® V3 Sectional Matrix System Starter Kit
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	++D002MATRIXSYSTEMSPX
EMDN code / description	Q01010199 - Dental Restoration Devices - Other
GMDN code / description	38786 - Dental matrix band, single use 33204 - Dental matrix band retainer (ring) 45007 - Dental wedge, single use 35851 - Rubber dam clamp forceps (forceps) 31814 - Dental dressing forceps, reusable (pin tweezer)
Intended purpose	The Palodent® V3 Sectional Matrix System is indicated for Class II restorations to facilitate the contouring of a direct placement restorative materials.
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.	

PALODENT® V3 SECTIONAL MATRIX SYSTEM DoC - DECLARATION OF CONFORMITY					
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External references (Common Specifications, Standards, Regulations) applied	TF024-LAER
EC Certificate	N/A
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF024

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


11/1/23

 Stacia Preston Date
 Regulatory Compliance Manager

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