



## Document Detail

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**Type:** 0070-Tech File DOC  
**Document No.:** 0070-TF024-DOC-11[6]  
**Title:** Palodent V3 Sectional Matrix System Declaration of Conformity  
**Comment:**  
**Status:** CURRENT  
**Effective Date:** 20-Sep-2022

## Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	19-Sep-2022 3:09 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	20-Sep-2022 12:05 pm	GMT

**PALODENT® V3 SECTIONAL MATRIX SYSTEM  
DoC - DECLARATION OF CONFORMITY**



**CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM**

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<b>Manufacturer:</b>	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
<b>Authorized EU-representative:</b>	Dentsply DeTrey GmbH, De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
<b>Authorized UK-representative:</b>	N/A
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>
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
<b>Classification and Rules (EU and UK)</b>	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
<b>Basic UDI-DI</b>	++D002MATRIXSYSTEMSPX
<b>Intended purpose:</b> The Palodent V3 Sectional Matrix System is intended to be used as a matrix to contain direct placement restorative materials in posterior cavities involving proximal surfaces.	
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH ANNEXES II and III. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
<b>Common Specifications applied:</b>	N/A
<b>Technical standards ref.:</b>	N/A
<b>EC Certificate:</b>	N/A
<b>UK Certificate</b>	N/A
<b>Reference to the corresponding Technical Documentation</b>	TF024
<b>Expiration date for the DoC</b>	N/A

**PALODENT® V3 SECTIONAL MATRIX SYSTEM  
DoC - DECLARATION OF CONFORMITY**



**CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM**

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

9/16/22

Stacia Preston  
Regulatory Affairs Manager

Date

<b>FORM NO</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	4
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