



Document Detail

Type: 0070-Tech File DOC
Document No.: 0070-TF024-DOC-2[18]
Title: Palodent 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® MATRIX SYSTEM
DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

RECORD NUMBER	MILFORD 0070-TF024-DOC-2	REVISION LEVEL	18	PAGE NO	Page 1 of 1
----------------------	--------------------------	-----------------------	----	----------------	-------------

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
659010	Palodent® Matrix System 100 Standard Matrices Refill
659015	Palodent® Matrix System 50 Standard Matrices Refill
659020	Palodent® Matrix System 50 Mini Matrices Refill
659040	Palodent® Matrix System 4 BiTine® Round Rings Refill
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)
Intended purpose	The Palodent® Matrix System is indicated whenever a restoration will involve interproximal surfaces to facilitate the contouring of a direct placement of restorative materials.
<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	TF024-LAER
EC Certificate	N/A
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF024

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

11/1/23

Stacia Preston
Regulatory Compliance Manager

Date

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