

Document Detail

Type: 0060-EC DT
Document No.: 0060-MDRDOC-0001-8[0]
Title: Declaration of Conformity - DS PMMA Multilayers Groot (MDR)
Comment:
Status: CURRENT
Effective Date: 18-Dec-2023

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
4000-QARA Approver York QARA Approver - York	Jonathan Coleman	15-Dec-2023 8:32 pm	GMT
0060-Document Control DPD Document Control	Lori Stern	18-Dec-2023 11:57 am	GMT

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
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Manufacturer:	Dentsply LLC 1301 Smile Way York, PA 17404 USA
	Single Registration Number (SRN): US-MF-000022592
Authorized EU-representative:	DeguDent GmbH Rodenbacher Chaussee 4 63457 Hanau-Wolfgang Germany
	Single Registration Number (SRN): DE-AR-000007938
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	NAME
Various – Reference attachment	DS PMMA Disc - Multilayer
Classification and Rules (EU)	EU Class: Class IIa following Rule 5, Non-Implantable According to Annex VIII of MDR 2017/745
Basic UDI-DI	++D001ACRYLICTEETH
EMDN code / description :	Q010299 - Prosthetic Dentistry Devices - Other
GMDN code / description :	38643 - Resin artificial teeth
Intended purpose :	Denture Teeth
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF</p> <ul style="list-style-type: none"> - THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX. <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	Refer to 4000-TEC-LAER-0002-2
EC certificate:	EC certificate number: MDR 753349 Notified Body name: BSI Group the Netherlands B.V. Notified Body address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands Notified Body ID: 2797 Certificate expiration date: 03-15-2028
UK Certificate	N/A
Reference to the corresponding Technical Documentation	Technical Documentation name: DS PMMA Multilayer discs Technical Documentation Index: 4000-TEC-INDEX-0002-2

York, PA, USA



 Jonathan Coleman
 Senior Manager, Quality and Regulatory

 12 DEC 2023
 Date:

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PRODUCT CODE / CATALOGUE NUMBER	NAME
8071012	Multilayer PMMA A1, 12mm
8071016	Multilayer PMMA A1, 16mm
8071020	Multilayer PMMA A1, 20mm
8071112	Multilayer PMMA A2, 12mm
8071116	Multilayer PMMA A2, 16mm
8071120	Multilayer PMMA A2, 20mm
8071212	Multilayer PMMA A3, 12mm
8071216	Multilayer PMMA A3, 16mm
8071220	Multilayer PMMA A3, 20mm
8071312	Multilayer PMMA A3.5, 12mm
8071316	Multilayer PMMA A3.5, 16mm
8071320	Multilayer PMMA A3.5, 20mm
8071412	Multilayer PMMA A4, 12mm
8071416	Multilayer PMMA A4, 16mm
8071420	Multilayer PMMA A4, 20mm
8071512	Multilayer PMMA B1, 12mm
8071516	Multilayer PMMA B1, 16mm
8071520	Multilayer PMMA B1, 20mm
8071612	Multilayer PMMA B2, 12mm
8071616	Multilayer PMMA B2, 16mm
8071620	Multilayer PMMA B2, 20mm
8071712	Multilayer PMMA B3, 12mm
8071716	Multilayer PMMA B3, 16mm
8071720	Multilayer PMMA B3, 20mm
8071812	Multilayer PMMA B4, 12mm
8071816	Multilayer PMMA B4, 16mm
8071820	Multilayer PMMA B4, 20mm
8071912	Multilayer PMMA C1, 12mm
8071916	Multilayer PMMA C1, 16mm
8071920	Multilayer PMMA C1, 20mm
8072012	Multilayer PMMA C2, 12mm
8072016	Multilayer PMMA C2, 16mm
8072020	Multilayer PMMA C2, 20mm

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8072112	Multilayer PMMA C3, 12mm
8072116	Multilayer PMMA C3, 16mm
8072120	Multilayer PMMA C3, 20mm
8072212	Multilayer PMMA C4, 12mm
8072216	Multilayer PMMA C4, 16mm
8072220	Multilayer PMMA C4, 20mm
8072312	Multilayer PMMA D2, 12mm
8072316	Multilayer PMMA D2, 16mm
8072320	Multilayer PMMA D2, 20mm
8072412	Multilayer PMMA D3, 12mm
8072416	Multilayer PMMA D3, 16mm
8072420	Multilayer PMMA D3, 20mm
8072512	Multilayer PMMA D4, 12mm
8072516	Multilayer PMMA D4, 16mm
8072520	Multilayer PMMA D4, 20mm
8072612	Multilayer PMMA HW2, 12mm
8072616	Multilayer PMMA HW2, 16mm
8072620	Multilayer PMMA HW2, 20mm

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REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	T. Oum	Initial MDR Declaration of Conformity.

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