

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM FORM					
DOCUMENT NUMBER	8000-FM-008-05	REVISION LEVEL	1	PAGE NO	Page 1 of 5

Manufacturer:	Dentsply Sirona 1301 Smile Way York, PA 17404
	Single registration number (SRN)-not available
Authorized EU-representative:	DeguDent GmbH Rodenbacher Chaussee 4 63457 Hanau-Wolfgang Germany
PRODUCT CODE / CATALOGUE NUMBER	NAME
Various – see attachment	DS PMMA Discs
Classification and Rules	Class IIa following Rule 8 ACCORDING TO ANNEX IX OF MDD 93/42/EEC
Basic UDI-DI	Not Available
Intended purpose: Temporary crown or resin	
THE ABOVE LISTED MEDICAL DEVICE(S) CONFORM TO THE REQUIREMENTS OF COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC AND MEET THE RELEVANT ESSENTIAL REQUIREMENTS OF ANNEX I. ALL DEVICES ARE DESIGNED, MANUFACTURED, AND TESTED AND RELEASED FOR SALE IN ACCORDANCE WITH THE TECHNICAL DOCUMENTATION. THIS DECLARATION IS MADE ON THE BASIS OF THE CERTIFICATE OF CONFORMITY CE01663 ISSUED BY BSI (IDENTIFICATION NUMBER 2797) IN ACCORDANCE WITH ANNEX II OF THE DIRECTIVE EXCLUDING SECTION 4. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
Harmonized Standards applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223-1:2016 DIN EN 1641:2010 EN 1041:2008 (Amd. 1:2013) EN 62366-1:2008 (2017)
Technical standards ref.:	ISO 10477:2018 Polymer-Based Crown and Veneering Materials
EC certificate:	Certificate no. CE 02100 BSI Group The Netherlands B.V. registered in the Netherlands under 33264284 BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

York PA USA

APR 01 2021

Signature Date: _____



Khyati Dave
Regulatory Affairs Manager



Lindsay Green
Vice President, Quality Assurance & Regulatory Compliance

REFERENCES

8000-SOP-008 - Technical Documentation

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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
8081012	Shaded PMMA A1, 12mm
8081016	Shaded PMMA A1, 16mm
8081020	Shaded PMMA A1, 20mm
8081025	Shaded PMMA A1, 25mm
8083112	Shaded PMMA A1T, 12mm
8083116	Shaded PMMA A1T, 16mm
8083120	Shaded PMMA A1T, 20mm
8081112	Shaded PMMA A2, 12mm
8081116	Shaded PMMA A2, 16mm
8081120	Shaded PMMA A2, 20mm
8081125	Shaded PMMA A2, 25mm
8081212	Shaded PMMA A3, 12mm
8081216	Shaded PMMA A3, 16mm
8081220	Shaded PMMA A3, 20mm
8081225	Shaded PMMA A3, 25mm
8081312	Shaded PMMA A3.5, 12mm

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8081316	Shaded PMMA A3.5, 16mm
8081320	Shaded PMMA A3.5, 20mm
8081412	Shaded PMMA A4, 12mm
8081416	Shaded PMMA A4, 16mm
8081420	Shaded PMMA A4, 20mm
8081512	Shaded PMMA B1, 12mm
8081516	Shaded PMMA B1, 16mm
8081520	Shaded PMMA B1, 20mm
8081525	Shaded PMMA B1, 25mm
8083212	Shaded PMMA B1T, 12mm
8083216	Shaded PMMA B1T, 16mm
8083220	Shaded PMMA B1T, 20mm
8081612	Shaded PMMA B2, 12mm
8081616	Shaded PMMA B2, 16mm
8081620	Shaded PMMA B2, 20mm
8081712	Shaded PMMA B3, 12mm
8081716	Shaded PMMA B3, 16mm
8081720	Shaded PMMA B3, 20mm
8081812	Shaded PMMA B4, 12mm
8081816	Shaded PMMA B4, 16mm
8081820	Shaded PMMA B4, 20mm
8081912	Shaded PMMA C1, 12mm
8081916	Shaded PMMA C1, 16mm
8081920	Shaded PMMA C1, 20mm
8081925	Shaded PMMA C1, 25mm
8082012	Shaded PMMA C2, 12mm
8082016	Shaded PMMA C2, 16mm
8082020	Shaded PMMA C2, 20mm
8082112	Shaded PMMA C3, 12mm
8082116	Shaded PMMA C3, 16mm
8082120	Shaded PMMA C3, 20mm
8082212	Shaded PMMA C4, 12mm
8082216	Shaded PMMA C4, 16mm
8082220	Shaded PMMA C4, 20mm

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8082312	Shaded PMMA D2, 12mm
8082316	Shaded PMMA D2, 16mm
8082320	Shaded PMMA D2, 20mm
8082412	Shaded PMMA D3, 12mm
8082416	Shaded PMMA D3, 16mm
8082420	Shaded PMMA D3, 20mm
8082512	Shaded PMMA D4, 12mm
8082516	Shaded PMMA D4, 16mm
8082520	Shaded PMMA D4, 20mm
8082612	Shaded PMMA HW2, 12mm
8082616	Shaded PMMA HW2, 16mm
8082620	Shaded PMMA HW2, 20mm
8082625	Shaded PMMA HW2, 25mm

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