

<b>DoC - DECLARATION OF CONFORMITY</b>					
<b>CONSUMABLE GROUP QUALITY SYSTEM FORM</b>					
<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 1 of 7

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
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>
Various – see attachment	Celtra Ceram
Classification and Rules	Class IIa following Rule 8 ACCORDING TO ANNEX IX OF MDD 93/42/EEC
Basic UDI-DI	Not Available
Intended purpose: Crown and bridge porcelain	
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 6872:2015 (Amd. 1:2018) Dentistry - Ceramic 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

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

<b>DoC - DECLARATION OF CONFORMITY</b>					
<b>CONSUMABLE GROUP QUALITY SYSTEM FORM</b>					
<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 2 of 7

**PRODUCT CODE / CATALOGUE NUMBER      NAME**

615401	Celtra Ceram Add-on Correction - C1, Light, 15G
650401	Celtra Ceram Add-on Correction - C1, Light, 50G
615402	Celtra Ceram Add-on Correction - C2, Medium, 15G
650402	Celtra Ceram Add-on Correction - C2, Medium, 50G
615403	Celtra Ceram Add-on Correction - C3, Dark, 15G
650403	Celtra Ceram Add-on Correction - C3, Dark, 50G
615404	Celtra Ceram Add-on Correction - C4, Transparent, 15G
650404	Celtra Ceram Add-on Correction - C4, Transparent, 50G
615411	Celtra Ceram Add-on Gingiva - G1, Pink, 15G
650411	Celtra Ceram Add-on Gingiva - G1, Pink, 50G
615412	Celtra Ceram Add-on Gingiva - G2, Reddish-pink, 15G
650412	Celtra Ceram Add-on Gingiva - G2, Reddish-pink, 50G
615413	Celtra Ceram Add-on Gingiva - G3, Salmon, 15G
650413	Celtra Ceram Add-on Gingiva - G3, Salmon, 50G
615414	Celtra Ceram Add-on Gingiva - G4, Dark, 15G
650414	Celtra Ceram Add-on Gingiva - G4, Dark, 50G
615415	Celtra Ceram Add-on Gingiva - G5, Mahogany, 15G
600603	Celtra Ceram Aesthetic Kit
600601	Celtra Ceram Basic Kit
615700	Celtra Ceram Dentin - 101, 15G
615701	Celtra Ceram Dentin - 102, 15G
615702	Celtra Ceram Dentin - 203, 15G
615703	Celtra Ceram Dentin - 204, 15G
615704	Celtra Ceram Dentin - 205, 15G
615705	Celtra Ceram Dentin - 206, 15G
615706	Celtra Ceram Dentin - 207, 15G
615707	Celtra Ceram Dentin - 208, 15G
615708	Celtra Ceram Dentin - 209, 15G
615709	Celtra Ceram Dentin - 310, 15G
615710	Celtra Ceram Dentin - 311, 15G
615711	Celtra Ceram Dentin - 312, 15G
615712	Celtra Ceram Dentin - 313, 15G
615713	Celtra Ceram Dentin - 314, 15G
615714	Celtra Ceram Dentin - 315, 15G
615715	Celtra Ceram Dentin - 316, 15G
615716	Celtra Ceram Dentin - 417, 15G

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

**DoC - DECLARATION OF CONFORMITY****CONSUMABLE GROUP QUALITY SYSTEM FORM**

<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 3 of 7
------------------------	----------------	-----------------------	---	----------------	-------------

615717	Celtra Ceram Dentin - 418, 15G
615718	Celtra Ceram Dentin - 419, 15G
615719	Celtra Ceram Dentin - 420, 15G
615720	Celtra Ceram Dentin - 421, 15G
615721	Celtra Ceram Dentin - 422, 15G
615722	Celtra Ceram Dentin - 423, 15G
615723	Celtra Ceram Dentin - 524, 15G
615724	Celtra Ceram Dentin - 525, 15G
615725	Celtra Ceram Dentin - 526, 15G
615134	Celtra Ceram Dentin - A1, 15G
650134	Celtra Ceram Dentin - A1, 50G
615135	Celtra Ceram Dentin - A2, 15G
650135	Celtra Ceram Dentin - A2, 50G
615136	Celtra Ceram Dentin - A3, 15G
650136	Celtra Ceram Dentin - A3, 50G
615137	Celtra Ceram Dentin - A3.5, 15G
650137	Celtra Ceram Dentin - A3.5, 50G
615138	Celtra Ceram Dentin - A4, 15G
650138	Celtra Ceram Dentin - A4, 50G
615139	Celtra Ceram Dentin - B1, 15G
650139	Celtra Ceram Dentin - B1, 50G
615140	Celtra Ceram Dentin - B2, 15G
650140	Celtra Ceram Dentin - B2, 50G
615141	Celtra Ceram Dentin - B3, 15G
650141	Celtra Ceram Dentin - B3, 50G
615142	Celtra Ceram Dentin - B4, 15G
650142	Celtra Ceram Dentin - B4, 50G
615130	Celtra Ceram Dentin - BL1, 15G
650130	Celtra Ceram Dentin - BL1, 50G
615131	Celtra Ceram Dentin - BL2, 15G
650131	Celtra Ceram Dentin - BL2, 50G
615132	Celtra Ceram Dentin - BL3, 15G
650132	Celtra Ceram Dentin - BL3, 50g
615133	Celtra Ceram Dentin - BL4, 15G
650133	Celtra Ceram Dentin - BL4, 50G
615143	Celtra Ceram Dentin - C1, 15G
650143	Celtra Ceram Dentin - C1, 50G

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

**DoC - DECLARATION OF CONFORMITY****CONSUMABLE GROUP QUALITY SYSTEM FORM**

<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 4 of 7
------------------------	----------------	-----------------------	---	----------------	-------------

615144	Celtra Ceram Dentin - C2, 15G
650144	Celtra Ceram Dentin - C2, 50G
615145	Celtra Ceram Dentin - C3, 15G
650145	Celtra Ceram Dentin - C3, 50G
615146	Celtra Ceram Dentin - C4, 15G
650146	Celtra Ceram Dentin - C4, 50G
615147	Celtra Ceram Dentin - D2, 15G
650147	Celtra Ceram Dentin - D2, 50G
615148	Celtra Ceram Dentin - D3, 15G
650148	Celtra Ceram Dentin - D3, 50G
615149	Celtra Ceram Dentin - D4, 15G
650149	Celtra Ceram Dentin - D4, 50G
650163	Celtra Ceram Dentin Effect - DE3, Grey, 50G
615161	Celtra Ceram Dentin Effect - DE1, Blue, 15G
650161	Celtra Ceram Dentin Effect - DE1, Blue, 50G
615162	Celtra Ceram Dentin Effect - DE2, Green-brown, 15G
650162	Celtra Ceram Dentin Effect - DE2, Green-brown, 50G
615163	Celtra Ceram Dentin Effect - DE3, Grey, 15G
615164	Celtra Ceram Dentin Effect - DE4, Orange-brown, 15G
650164	Celtra Ceram Dentin Effect - DE4, Orange-brown, 50G
615165	Celtra Ceram Dentin Effect - DE5, Pink, 15G
650165	Celtra Ceram Dentin Effect - DE5, Pink, 50G
615166	Celtra Ceram Dentin Effect - DE6, Violet, 15G
650166	Celtra Ceram Dentin Effect - DE6, Violet, 50G
615167	Celtra Ceram Dentin Effect - DE7, Yellow, 15G
650167	Celtra Ceram Dentin Effect - DE7, Yellow, 50G
615168	Celtra Ceram Dentin Effect - DE8, White, 15G
650168	Celtra Ceram Dentin Effect - DE8, White, 50G
615169	Celtra Ceram Dentin Effect - DE9, Orange, 15G
650169	Celtra Ceram Dentin Effect - DE9, Orange, 50G
615171	Celtra Ceram Dentin Gingiva - DG1, Pink, 15G
650171	Celtra Ceram Dentin Gingiva - DG1, Pink, 50G
615172	Celtra Ceram Dentin Gingiva - DG2, Reddish-Pink, 15G
650172	Celtra Ceram Dentin Gingiva - DG2, Reddish-pink, 50G
615173	Celtra Ceram Dentin Gingiva - DG3, Salmon, 15G
650173	Celtra Ceram Dentin Gingiva - DG3, Salmon, 50G
615174	Celtra Ceram Dentin Gingiva - DG4, Dark, 15G

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

**DoC - DECLARATION OF CONFORMITY**



**CONSUMABLE GROUP QUALITY SYSTEM FORM**

<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 5 of 7
------------------------	----------------	-----------------------	---	----------------	-------------

650174	Celtra Ceram Dentin Gingiva - DG4, Dark, 50G
615175	Celtra Ceram Dentin Gingiva - DG5, Mahogany, 15G
650175	Celtra Ceram Dentin Gingiva - DG5, Mahogany, 50G
615201	Celtra Ceram Enamel - E1, Extra-light, 15G
650201	Celtra Ceram Enamel - E1, Extra-light, 50G
615202	Celtra Ceram Enamel - E2, Light, 15G
650202	Celtra Ceram Enamel - E2, Light, 50G
615203	Celtra Ceram Enamel - E3, Medium, 15G
650203	Celtra Ceram Enamel - E3, Medium, 50G
615204	Celtra Ceram Enamel - E4, Transparent, 15G
650204	Celtra Ceram Enamel - E4, Transparent, 50G
615205	Celtra Ceram Enamel - E5, White, 15G
650205	Celtra Ceram Enamel - E5, White, 50G
615206	Celtra Ceram Enamel - E6, Dark, 15G
650206	Celtra Ceram Enamel - E6, Dark, 50G
615221	Celtra Ceram Enamel Effect - EE1, Sunrise, 15G
650221	Celtra Ceram Enamel Effect - EE1, Sunrise, 50G
615222	Celtra Ceram Enamel Effect - EE2, Violet, 15G
650222	Celtra Ceram Enamel Effect - EE2, Violet, 50G
615223	Celtra Ceram Enamel Effect - EE3, Sunset, 15G
650223	Celtra Ceram Enamel Effect - EE3, Sunset, 50G
615224	Celtra Ceram Enamel Effect - EE4, Fog, 15G
650224	Celtra Ceram Enamel Effect - EE4, Fog, 50G
615225	Celtra Ceram Enamel Effect - EE5, Sky, 15G
650225	Celtra Ceram Enamel Effect - EE5, Sky, 50G
615226	Celtra Ceram Enamel Effect - EE6, Ivory, 15G
650226	Celtra Ceram Enamel Effect - EE6, Ivory, 50G
615211	Celtra Ceram Enamel Opal - EO1, Extra-light, 15G
650211	Celtra Ceram Enamel Opal - EO1, Extra-light, 50G
615212	Celtra Ceram Enamel Opal - EO2, Light, 15G
650212	Celtra Ceram Enamel Opal - EO2, Light, 50G
615213	Celtra Ceram Enamel Opal - EO3, Medium, 15G
650213	Celtra Ceram Enamel Opal - EO3, Medium, 50G
615214	Celtra Ceram Enamel Opal - EO4, Transparent, 15G
650214	Celtra Ceram Enamel Opal - EO4, Transparent, 50G
615215	Celtra Ceram Enamel Opal - EO5, HT, 15G
650215	Celtra Ceram Enamel Opal - EO5, HT, 50G

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

**DoC - DECLARATION OF CONFORMITY****CONSUMABLE GROUP QUALITY SYSTEM FORM**

<b>DOCUMENT NUMBER</b>	8000-FM-008-05	<b>REVISION LEVEL</b>	1	<b>PAGE NO</b>	Page 6 of 7
------------------------	----------------	-----------------------	---	----------------	-------------

615216	Celtra Ceram Enamel Opal - EO6, LT, 15G
650216	Celtra Ceram Enamel Opal - EO6, LT, 50G
600604	Celtra Ceram Gingiva Kit
615150	Celtra Ceram Opaceous Dentin - OD0, 15G
615151	Celtra Ceram Opaceous Dentin - OD1, 15G
615152	Celtra Ceram Opaceous Dentin - OD2, 15G
615153	Celtra Ceram Opaceous Dentin - OD3, 15G
615154	Celtra Ceram Opaceous Dentin - OD4, 15G
615155	Celtra Ceram Opaceous Dentin - OD5, 15G
615156	Celtra Ceram Opaceous Dentin - OD6, 15G
615181	Celtra Ceram Power Dentin - PD1, 15G
650181	Celtra Ceram Power Dentin - PD1, 50G
615182	Celtra Ceram Power Dentin - PD2, 15G
650182	Celtra Ceram Power Dentin - PD2, 50G
615183	Celtra Ceram Power Dentin - PD3, 15G
650183	Celtra Ceram Power Dentin - PD3, 50G
615184	Celtra Ceram Power Dentin - PD4, 15G
650184	Celtra Ceram Power Dentin - PD4, 50G
615185	Celtra Ceram Power Dentin - PD5, 15G
650185	Celtra Ceram Power Dentin - PD5, 50G
615186	Celtra Ceram Power Dentin - PD6, 15G
650186	Celtra Ceram Power Dentin - PD6, 50G
600605	Celtra Ceram Shade Series Kit
600602	Celtra Ceram Trial Kit
650700	CELTRA® CERAM Dentin 101, 50G
650701	CELTRA® CERAM Dentin 102, 50G
650702	CELTRA® CERAM Dentin 203, 50G
650703	CELTRA® CERAM Dentin 204, 50G
650704	CELTRA® CERAM Dentin 205, 50G
650705	CELTRA® CERAM Dentin 206, 50G
650706	CELTRA® CERAM Dentin 207, 50G
650707	CELTRA® CERAM Dentin 208, 50G
650708	CELTRA® CERAM Dentin 209, 50G
650709	CELTRA® CERAM Dentin 310, 50G
650710	CELTRA® CERAM Dentin 311, 50G
650711	CELTRA® CERAM Dentin 312, 50G
650712	CELTRA® CERAM Dentin 313, 50G

<b>TEMPLATE NO</b>	8000-Template-003	<b>REVISION LEVEL</b>	0
--------------------	-------------------	-----------------------	---

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM FORM					
DOCUMENT NUMBER	8000-FM-008-05	REVISION LEVEL	1	PAGE NO	Page 7 of 7

650713	CELTRA® CERAM Dentin 314, 50G
650714	CELTRA® CERAM Dentin 315, 50G
650715	CELTRA® CERAM Dentin 316, 50G
650716	CELTRA® CERAM Dentin 417, 50G
650717	CELTRA® CERAM Dentin 418, 50G
650718	CELTRA® CERAM Dentin 419, 50G
650719	CELTRA® CERAM Dentin 420, 50G
650720	CELTRA® CERAM Dentin 421, 50G
650721	CELTRA® CERAM Dentin 422, 50G
650722	CELTRA® CERAM Dentin 423, 50G
650723	CELTRA® CERAM Dentin 524, 50G
650724	CELTRA® CERAM Dentin 525, 50G
650725	CELTRA® CERAM Dentin 526, 50G

TEMPLATE NO	8000-Template-003	REVISION LEVEL	0
-------------	-------------------	----------------	---