

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

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 Stains and Overglze
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 stain and glaze 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

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PRODUCT CODE / CATALOGUE NUMBER	NAME
605520	Universal Body Stain - S0, 5G
605521	Universal Body Stain - S1, 5G
605522	Universal Body Stain - S2, 5G
605523	Universal Body Stain - S3, 5G
605524	Universal Body Stain - S4, 5G
605531	Universal Incisal Stain - i1, 5G
605532	Universal Incisal Stain - i2, 5G
615542	Universal Overglaze - High Flu, 15G
605542	Universal Overglaze - High Flu, 5G
615540	Universal Overglaze, 15G
605540	Universal Overglaze, 5G
605512	Universal Stain - Blue, 5G
605511	Universal Stain - Chestnut, 5G
605503	Universal Stain - Copper, 5G
605501	Universal Stain - Crème, 5G
605510	Universal Stain - Grey, 5G
605504	Universal Stain - Khaki, 5G
605506	Universal Stain - Mahogany, 5G
605505	Universal Stain - Olive, 5G
605513	Universal Stain - Pink, 5G
605509	Universal Stain - Purple, 5G
605508	Universal Stain - Raspberry, 5G
605502	Universal Stain - Sunset, 5G
605507	Universal Stain - Violet, 5G
605500	Universal Stain - White, 5G
600700	Universal Stain and Overglaze Kit

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