



Document Detail

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Title: Declaration of Conformity - Lucitone Digital Print System MDR
Comment:
Status: CURRENT
Effective Date: 20-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	19-Dec-2023 9:17 pm	GMT
0060-Document Control DPD Document Control	Lori Stern	20-Dec-2023 11:09 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:	DequDent 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
906200	Lucitone Digital Print™ 3D Denture Resin – Original, 1 bottle (1 kg)
906201	Lucitone Digital Print™ 3D Denture Resin – Original Opaque, 1 bottle (1 kg)
906202	Lucitone Digital Print™ 3D Denture Resin – Light, 1 bottle (1 kg)
906203	Lucitone Digital Print™ 3D Denture Resin – Light Reddish Pink, 1 bottle (1 kg)
906204	Lucitone Digital Print™ 3D Denture Resin – Dark Reddish Pink, 1 bottle (1 kg)
906220	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement A1 - 1 Bottle (1kg)
906221	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement A2 - 1 Bottle (1kg)
906222	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement A3 - 1 Bottle (1kg)
906223	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement B1 - 1 Bottle (1kg)
906224	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement B2 - 1 Bottle (1kg)
906225	Lucitone Digital Value™ - 3D Economy Tooth & Trial Placement BL3 - 1 Bottle (1kg)
906381	Lucitone Digital IPN 3D Premium Tooth - Shade A1 - 500 ML
906382	Lucitone Digital IPN 3D Premium Tooth - Shade A2 - 500 ML
906383	Lucitone Digital IPN 3D Premium Tooth - Shade A3 - 500 ML
906384	Lucitone Digital IPN 3D Premium Tooth - Shade A3.5 - 500 ML
906385	Lucitone Digital IPN 3D Premium Tooth - Shade A4 - 500 ML
906386	Lucitone Digital IPN 3D Premium Tooth - Shade B1 - 500 ML
906387	Lucitone Digital IPN 3D Premium Tooth - Shade B2 - 500 ML
906388	Lucitone Digital IPN 3D Premium Tooth - Shade B3 - 500 ML
906389	Lucitone Digital IPN 3D Premium Tooth - Shade B4 - 500 ML
906390	Lucitone Digital IPN 3D Premium Tooth - Shade C1 - 500 ML
906391	Lucitone Digital IPN 3D Premium Tooth - Shade C2 - 500 ML
906392	Lucitone Digital IPN 3D Premium Tooth - Shade C3 - 500 ML
906393	Lucitone Digital IPN 3D Premium Tooth - Shade C4 - 500 ML
906394	Lucitone Digital IPN 3D Premium Tooth - Shade D2 - 500 ML
906395	Lucitone Digital IPN 3D Premium Tooth - Shade D3 - 500 ML
906396	Lucitone Digital IPN 3D Premium Tooth - Shade D4 - 500 ML
906397	Lucitone Digital IPN 3D Premium Tooth - Shade BL1 - 500 ML
906398	Lucitone Digital IPN 3D Premium Tooth - Shade BL3 - 500 ML
906413	Primeprint Lucitone Digital IPN Premium Tooth 500ml B13
906412	Primeprint Lucitone Digital IPN Premium Tooth 500ml C1
906411	Primeprint Lucitone Digital IPN Premium Tooth 500ml B2
906410	Primeprint Lucitone Digital IPN Premium Tooth 500ml B1
906409	Primeprint Lucitone Digital IPN Premium Tooth 500ml A3.5
906408	Primeprint Lucitone Digital IPN Premium Tooth 500ml A3
906407	Primeprint Lucitone Digital IPN Premium Tooth 500ml A2
906406	Primeprint Lucitone Digital IPN Premium Tooth 500ml A1
906405	Primeprint Lucitone Digital Value Trial Placement A1
906404	Primeprint Lucitone Digital Print Denture Base Dark Reddish Pink
906403	Primeprint Lucitone Digital Print Denture Base Light Reddish Pink
906402	Primeprint Lucitone Digital Print Denture Base Light
906401	Primeprint Lucitone Digital Print Denture Base Original
906399	Lucitone Digital Fuse Step 3 Total - Size - 15 ML
906185	Lucitone Digital Fuse™ Step 1 – 3D Tooth Conditioning Agent (180g bottle)
906186	Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Agent – Original (25g bottle)
906187	Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Agent – Original Opaque (25g bottle)

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906188	Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Agent – Light (25g bottle)	
906189	Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Agent – Light Reddish Pink (25g bottle)	
906190	Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Agent – Dark Reddish Pink (25g bottle)	
906195	Lucitone Digital Fuse™ Step 3 – 3D Denture Sealer (15mL bottle)	
906245	Lucitone Digital Fuse™ Bonding Kit	
Classification and Rules (EU and UK)	EU Class: Class IIa following Rule 5, Non-Implantable According to Annex VIII of MDR 2017/745	
Basic UDI-DI	++D001ACRYLICTEETH ++D001DENTBASENAPPLCG	
EMDN code / description :	Q010299 - Prosthetic Dentistry Devices - Other	
GMDN code / description :	38643 - Resin Artificial teeth 16730 - Dental appliance fabrication material, cured	
Intended purpose:	Device is intended for fabrication of removable dental prostheses to restore function and aesthetics.	
<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-0003-3	
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	Technical Documentation Index
	Lucitone Digital Print	4000-TEC-INDEX-0003-3
	Lucitone Digital Value	4000-TEC-INDEX-0001-3
	Lucitone Digital IPN	4000-TEC-INDEX-0001-4
	Lucitone Digital Print Denture System for Primeprint	4000-TEC-INDEX-0003-5

York, PA, USA



 Jonathan Coleman
 Senior Manager, Quality and Regulatory

19 DEC 2023

 Date:

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REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	T. Oum	Initial MDR Declaration of Conformity. Removed SKUs 906191 and 906192 – Marketing decided to not launch in EU at this time.
1	T. Oum	Removed extra number in shade D4 of Lucitone Digital IPN 3D.