

Document Detail

Type: 0060-EC DT
Document No.: 0060-MDRDOC-0003-4[0]
Title: Declaration of Conformity - Lucitone Digital Fit Discs (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
906114	Lucitone Digital Fit Denture Base Disc LITE-20
906118	Lucitone Digital Fit Denture Base Disc LRP-20
906134	Lucitone Digital Fit Denture Base Disc PINK-20
906122	Lucitone Digital Fit Denture Base Disc DP-20
906130	Lucitone Digital Fit Denture Base Disc P.OPQ-20
906126	Lucitone Digital Fit Denture Base Disc O.OPQ-20
906110	Lucitone Digital Fit Denture Base Disc OR-20
906115	Lucitone Digital Fit Denture Base Disc LITE-25
906119	Lucitone Digital Fit Denture Base Disc LRP-25
906135	Lucitone Digital Fit Denture Base Disc PINK-25
906123	Lucitone Digital Fit Denture Base Disc DP-25
906131	Lucitone Digital Fit Denture Base Disc P.OPQ-25
906127	Lucitone Digital Fit Denture Base Disc O.OPQ-25
906111	Lucitone Digital Fit Denture Base Disc OR-25
906116	Lucitone Digital Fit Denture Base Disc LITE-30
906120	Lucitone Digital Fit Denture Base Disc LRP-30
906136	Lucitone Digital Fit Denture Base Disc PINK-30
906124	Lucitone Digital Fit Denture Base Disc DP-30
906132	Lucitone Digital Fit Denture Base Disc P.OPQ-30
906128	Lucitone Digital Fit Denture Base Disc O.OPQ-30
906112	Lucitone Digital Fit Denture Base Disc OR-30
906117	Lucitone Digital Fit Denture Base Disc LITE-35
906121	Lucitone Digital Fit Denture Base Disc LRP-35
906137	Lucitone Digital Fit Denture Base Disc PINK-35
906125	Lucitone Digital Fit Denture Base Disc DP-35
906133	Lucitone Digital Fit Denture Base Disc P.OPQ-35
906129	Lucitone Digital Fit Denture Base Disc O.OPQ-35
906113	Lucitone Digital Fit Denture Base Disc OR-35
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	++D001DENTBASENAPPLCG
EMDN code / description :	Q010299 - Prosthetic Dentistry Devices - Other
GMDN code / description :	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-0003-4
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

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UK Certificate	N/A
Reference to the corresponding Technical Documentation	Technical Documentation name: Lucitone Digital Fit Discs Technical Documentation Index: 4000-TEC-INDEX-0003-4

York, PA, USA




Jonathan Coleman
Senior Manager, Quality and Regulatory

12 DEC 2023

Date:

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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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