

Document Detail

Type: 0060-EC DT
Document No.: 0060-MDRDOC-0003-1[0]
Title: Declaration of Conformity - Lucitone 199 (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					
DOCUMENT NUMBER	0060-MDRDOC-0003-1	REVISION LEVEL	0	PAGE NO	Page 1 of 3

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
688107	Lucitone 199® 50-Unit College Package Original Shade
688420	Lucitone 199® Denture Base Resin - 108 Unit Powder Economy Pack (5 lb.) - Dark Pink
688220	Lucitone 199® Denture Base Resin - 108 Unit Powder Economy Pack (5 lb.) - Light
688320	Lucitone 199® Denture Base Resin - 108 Unit Powder Economy Pack (5 lb.) - Light Reddish Pink
688120	Lucitone 199® Denture Base Resin - 108 Unit Powder Economy Pack (5 lb.) - Original Shade
688403	Lucitone 199® Denture Base Resin - 11 Unit Package - Dark Pink
688203	Lucitone 199® Denture Base Resin - 11 Unit Package - Light
688303	Lucitone 199® Denture Base Resin - 11 Unit Package - Light Reddish Pink
688103	Lucitone 199® Denture Base Resin - 11 Unit Package - Original Shade
688405	Lucitone 199® Denture Base Resin - 120 Unit Package - Dark Pink
688205	Lucitone 199® Denture Base Resin - 120 Unit Package - Light
688305	Lucitone 199® Denture Base Resin - 120 Unit Package - Light Reddish Pink
688105	Lucitone 199® Denture Base Resin - 120 Unit Package - Original Shade
688406	Lucitone 199® Denture Base Resin - 30 Unit Powder (630g) - Dark Pink
688206	Lucitone 199® Denture Base Resin - 30 Unit Powder (630g) - Light
688306	Lucitone 199® Denture Base Resin - 30 Unit Powder (630g) - Light Reddish Pink
688106	Lucitone 199® Denture Base Resin - 30 Unit Powder (630g) - Original Shade
688411	Lucitone 199® Denture Base Resin - 540 Unit Powder (25 lb.) - Dark Pink
688211	Lucitone 199® Denture Base Resin - 540 Unit Powder (25 lb.) - Light
688311	Lucitone 199® Denture Base Resin - 540 Unit Powder (25 lb.) - Light Reddish Pink
688111	Lucitone 199® Denture Base Resin - 540 Unit Powder (25 lb.) - Original Shade
684315	Lucitone® Liquid - 3785 mL (1 gal. Shipped in Four 1 qt. Containers)
684309	Lucitone® Liquid - 430 mL (14.5 fl. Oz.)
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 THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX.</p> <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-0003-1
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: Lucitone 199 Technical Documentation Index: 4000-TEC-INDEX-0003-1

TEMPLATE NO	8000-FM-008-05	REVISION LEVEL	6
--------------------	----------------	-----------------------	---

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	0060-MDRDOC-0003-1	REVISION LEVEL	0	PAGE NO	Page 2 of 3

York, PA, USA



 Jonathan Coleman
 Senior Manager, Quality and Regulatory

12 DEC 2023

 Date:

TEMPLATE NO	8000-FM-008-05	REVISION LEVEL	6
--------------------	----------------	-----------------------	---

DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	0060-MDRDOC-0003-1	REVISION LEVEL	0	PAGE NO	Page 3 of 3

REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	T. Oum	Initial MDR Declaration of Conformity.

TEMPLATE NO	8000-FM-008-05	REVISION LEVEL	6
--------------------	----------------	-----------------------	---