Document Detail

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Title: Declaration of Conformity - Lucitone HIPA (MDR)

Comment:

Status: CURRENT

Effective Date: 18-Dec-2023

Approval

Owner Role	Sign-off By	Sign-off Date	
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

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**
682014	Lucitone® HIPA Denture Base Liquid 1000mL Package
682015	Lucitone® HIPA Denture Base Liquid 4x1000mL Package
682012	Lucitone® HIPA Denture Base Liquid 500mL Package
906021	Lucitone® HIPA Denture Base Powder Dark Pink 10000g Package
905935	Lucitone® HIPA Denture Base Powder Dark Pink 1000g Package
905945	Lucitone® HIPA Denture Base Powder Dark Pink 2000g Package
905925	Lucitone® HIPA Denture Base Powder Dark Pink 500g Package
906019	Lucitone® HIPA Denture Base Powder Light 10000g Package
905933	Lucitone® HIPA Denture Base Powder Light Pink 1000g Package
905943	Lucitone® HIPA Denture Base Powder Light Pink 2000g Package
905923	Lucitone® HIPA Denture Base Powder Light Pink 500g Package
906020	Lucitone® HIPA Denture Base Powder Light Reddish Pink 10000g Package
905934	Lucitone® HIPA Denture Base Powder Light Reddish Pink 1000g Package
905944	Lucitone® HIPA Denture Base Powder Light Reddish Pink 2000g Package
905924	Lucitone® HIPA Denture Base Powder Light Reddish Pink 500g Package
906018	Lucitone® HIPA Denture Base Powder Original 10000g Package
905932	Lucitone® HIPA Denture Base Powder Original 1000g Package
905942	Lucitone® HIPA Denture Base Powder Original 2000g Package
905922	Lucitone® HIPA Denture Base Powder Original 500g Package
906022	Lucitone® HIPA Denture Base Powder Original Opaque 10000g Package
905954	Lucitone® HIPA Denture Base Powder Original Opaque 1000g Package
905956	Lucitone® HIPA Denture Base Powder Original Opaque 2000g Package
905952	Lucitone® HIPA Denture Base Powder Original Opaque 500g Package
905936	Lucitone® HIPA Denture Base Powder Pink 1000g Package
905946	Lucitone® HIPA Denture Base Powder Pink 2000g Package
905926	Lucitone® HIPA Denture Base Powder Pink 500g Package
905937	Lucitone® HIPA Denture Base Powder Pink Intensive 1000g Package
905947	Lucitone® HIPA Denture Base Powder Pink Intensive 2000g Package
905927	Lucitone® HIPA Denture Base Powder Pink Intensive 500g Package
905939	Lucitone® HIPA Denture Base Powder Pink Natural 1000g Package
905949	Lucitone® HIPA Denture Base Powder Pink Natural 2000g Package
905929	Lucitone® HIPA Denture Base Powder Pink Natural 500g Package
905938	Lucitone® HIPA Denture Base Powder Pink Opaque 1000g Package
905948	Lucitone® HIPA Denture Base Powder Pink Opaque 2000g Package
905928	Lucitone® HIPA Denture Base Powder Pink Opaque 500g Package
905960	Lucitone® HIPA Trial Kit Original 100g Package
905900	Lucitone® HIPA Trial Kit Original Opaque 100g/ml Package
905965	Lucitone® HIPA Trial Kit Pink 100g Package
682016	Lucitone® HIPA Liquid 473 ml
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

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. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
External references (Common Specifications, Standards, Regulations) applied	Refer to 4000-TEC-LAER-0003-2
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 HIPA Technical Documentation Index: 4000-TEC-INDEX-0003-2

York, PA, USA

Jonathan Coleman
Senior Manager, Quality and Regulatory

12 DEC 2023
Date:

REVISION HISTORY

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