

Document Detail

Type: 0060-EC DT
Document No.: 0060-MDRDOC-109[0]
Title: Declaration of Conformity Prophy Paste Class 1
Comment:
Status: CURRENT
Effective Date: 16-Jan-2024

Approval

Owner Role	Sign-off By	Sign-off Date	
0060-Regulatory DPD Regulatory	Maysa Curti	15-Jan-2024 2:46 pm	GMT
0060-Head of QA/RA DPD Head of Quality Assurance and Regulatory Affairs	Jonathan Coleman	16-Jan-2024 1:30 pm	GMT
0060-Document Control DPD Document Control	Lori Stern	16-Jan-2024 2:55 pm	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:	Dentsply DeTrey De-Trey-Strasse 1, 78467 Konstanz, Germany
	Single registration number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	NAME
801171	NUPRO® Prophy Paste with Fluoride, Cherry, Coarse, 12 oz Jar
801306	NUPRO® Prophy Paste with Fluoride, Cookie Dough, Coarse
801212	NUPRO® Prophy Paste with Fluoride, Mint, Coarse
801211	NUPRO® Prophy Paste with Fluoride, Orange, Coarse
801111	NUPRO® Prophy Paste with Fluoride, Orange, Coarse, 12 oz Jar
801231	NUPRO® Prophy Paste with Fluoride, Orange, Fine
801221	NUPRO® Prophy Paste with Fluoride, Orange, Medium
801309	NUPRO® Prophy Paste with Fluoride, Razzberry, Coarse
801311	NUPRO® Prophy Paste with Fluoride, Razzberry, Fine
801310	NUPRO® Prophy Paste with Fluoride, Razzberry, Medium
801300	NUPRO® Prophy Paste, BubbleExtreme™, Coarse
801302	NUPRO® Prophy Paste, BubbleExtreme™, Fine
801301	NUPRO® Prophy Paste, BubbleExtreme™, Medium
801308	NUPRO® Prophy Paste, Cookie Dough, Fine
801307	NUPRO® Prophy Paste, Cookie Dough, Medium
801227	NUPRO® Prophy Paste, Grape, Coarse
801127	NUPRO® Prophy Paste, Grape, Coarse, 12 oz Jar
801225	NUPRO® Prophy Paste, Grape, Fine
801226	NUPRO® Prophy Paste, Grape, Medium
801126	NUPRO® Prophy Paste, Grape, Medium, 12oz Jar
801299	NUPRO® Prophy Paste, Mint Fluoride, Plus
801112	NUPRO® Prophy Paste, Mint, Coarse, 12 oz Jar
801232	NUPRO® Prophy Paste, Mint, Fine
801222	NUPRO® Prophy Paste, Mint, Medium
801122	NUPRO® Prophy Paste, Mint, Medium, 12 oz Jar
801514	NUPRO® Sensodyne® Prophy Paste, Citrus Mint, Polish
801520	NUPRO® Sensodyne® Prophy Paste, Citrus Mint, Polish
801515	NUPRO® Sensodyne® Prophy Paste, Citrus Mint, Stain Removal
801521	NUPRO® Sensodyne® Prophy Paste, Citrus Mint, Stain Removal
801522	NUPRO® Sensodyne® Prophy Paste, Orange, Polish
801534	NUPRO® Sensodyne® Prophy Paste, Orange, Polish
801523	NUPRO® Sensodyne® Prophy Paste, Orange, Stain Removal
801535	NUPRO® Sensodyne® Prophy Paste, Orange, Stain Removal, 12 oz Jar
801512	NUPRO® Sensodyne® Prophy Paste, Peppermint, Polish
801518	NUPRO® Sensodyne® Prophy Paste, Peppermint, Polish
801513	NUPRO® Sensodyne® Prophy Paste, Peppermint, Stain Removal
801519	NUPRO® Sensodyne® Prophy Paste, Peppermint, Stain Removal
801510	NUPRO® Sensodyne® Prophy Paste, Spearmint, Polish
801516	NUPRO® Sensodyne® Prophy Paste, Spearmint, Polish
801530	NUPRO® Sensodyne® Prophy Paste, Spearmint, Polish
801511	NUPRO® Sensodyne® Prophy Paste, Spearmint, Stain Removal
801517	NUPRO® Sensodyne® Prophy Paste, Spearmint, Stain Removal
801531	NUPRO® Sensodyne® Prophy Paste, Spearmint, Stain Removal, 12 oz Jar
Classification and Rules (EU and UK)	EU class: Class I following Rule 5 ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745
Basic UDI-DI :	++D003PROPASTEWITHFLUOS6

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EMDN code / description :	Q01010403 - DENTAL ABRASIVE AND POLISHING MATERIALS
GMDN code / description :	11168 Dentrifrice
Intended purpose:	Intended for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment
<p>WE HEREWITH DECLARE, UNDER OUR SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES 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 0060-TEC-LAER-109
EC Certificate.	N/A – Class I Device
UK Certificate	N/A
Reference to the corresponding Technical Documentation	Technical Documentation name: Fluoride Prophy Paste Technical Documentation Index: 0060-TEC-INDEX-109

1301 Smile Way, York, PA 17404 USA

Effective Date: 09 JAN 2024



 Jonathan Coleman
 Senior Manager Quality and Regulatory
 Signing as representative PRRC for legal manufacturer.

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REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	M. CURTI	First MDR DoC release

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