Declaration of Conformity
European Community Council

HySolate LPNP Latex Dental Dams

Revision History			
Revision	**Date**	**ECN#**	**Description of Change**
A	07/19/2022	21148	Initial Release
B	12/12/2022	21546	Updated to include all latex and non-latex dental dam products and accessories.
C	06/16/2023	21575	Added 60036125

Revised By: NS	App'L By: BLD	**Coltène/Whaledent Inc.** 235 ASCOT PARKWAY, CUYAHOGA FALLS, OH 44223			
Created By: CL	Date: 07/19/2022	DOC HySolate LPNP Dental Dam			
App'L By: TAC	Date: 07/19/2022	Sheet 1 of 6	Size C	Drawing No. **90621-205**	Rev. C

90621-205 Rev. C

DECLARATION OF CONFORMITY

Product:	**HySolate Dental Dams and Accessories**
Models:	**See attachment**
Basic UDI-DI:	**76303929DENTALDAMHZ Dental Dam, Latex and Non-Latex**
	76303929DDCLAMPLU Dental Dam Clamp
	76303929DDFORCEPSGX Dental Dam Forceps
	76303929DDFRAMENH Dental Dam Frame
	76303929DDNAPKINSGZ Dental Dam Napkin
	76303929DDPUNCHTV Dental Dam Punch
	76303929DDTEMPLATE7T Dental Dam Template
	76303929DDWEDJETSJZ Dental Dam Wedjet
	76303929DDKITMB Dental Dam Kits
Classification:	**Class I [(EU) 2017/745 Annex VIII, Rule *5*]**
Legal Manufacturer:	Coltene International Dental Group Dent4You AG Bahnhofstrasse 2 Ch-9435 Heerbrugg CHRN: CHRN-MF-20001009 SRN: <will be added once available>
European Representative:	Coltene/Whaledent GmbH + Co. KG Raiffeisenstrasse 30 89129 Langenau Germany SRN: DE-AR-000005719

We herewith declare that the above-mentioned products meet the provisions of the following legislation(s) and that Dent4You AG has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

General Applicable Legislation:

Medical Device Regulations: Regulation (EU) 2017/745 of April 2017 on medical devices (MDR 2017/745, Article 52)

Standards and Common Specifications:

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 10993-5:2009, EN ISO 10993-10:2010, ISO 10993-11, EN ISO 15223-1:2016, EN IEC 62366:2008, EN ISO 10993-1:2018, EN ISO 10993-1:2018, EN ISO 17664:2017

Notify Body:	TÜV SÜD Product Service GmbH Ridlerstraße65,

Dent 4 you

D-80339 München, Deutschland
Identification No. 0123

Certificate: N/A

Date of Effectiveness of Product Under this Declaration: July 26, 2023

Place: Cuyahoga Falls, OH, USA

Signature: _____ **Date:** 2023-07-20

Name & Title: Kelly Makimoto, Global Quality Manager

Part Number	MDR Class	Description of Finished Product or Item	Introduction Date
Latex Dental Dam			
60034424	I	HySolate Latex Dental Dam Light thin Child (5x5), 52 pcs	March 2022
60034425	I	HySolate Latex Dental Dam Light medium Child (5x5), 52 pcs	March 2022
60034426	I	HySolate Latex Dental Dam Light heavy Child (5x5), 52 pcs	March 2022
60034427	I	HySolate Latex Dental Dam Light thin Adult (6x6), 36 pcs	March 2022
60034428	I	HySolate Latex Dental Dam Light medium Adult (6x6), 36 pcs	March 2022
60034429	I	HySolate Latex Dental Dam Light heavy Adult (6x6), 36 pcs	March 2022
60034430	I	HySolate Latex Dental Dam Light x-heavy Adult (6x6), 36 pcs	March 2022
60034431	I	HySolate Latex Dental Dam Light medium Adult (6x6), 360 pcs	March 2022
60034432	I	HySolate Latex Dental Dam Light medium Child (5x5), 364 pcs	March 2022
60034414	I	HySolate Latex Dental Dam Green thin Child (5x5), 52 pcs	March 2022
60034415	I	HySolate Latex Dental Dam Green medium Child (5x5), 52 pcs	March 2022
60034416	I	HySolate Latex Dental Dam Green heavy Child (5x5), 52 pcs	March 2022
60034417	I	HySolate Latex Dental Dam Green x-heavy Child (5x5), 52 pcs	March 2022
60034418	I	HySolate Latex Dental Dam Green thin Adult (6x6), 36 pcs	March 2022
60034419	I	HySolate Latex Dental Dam Green medium Adult (6x6), 36 pcs	March 2022
60034420	I	HySolate Latex Dental Dam Green heavy Adult (6x6), 36 pcs	March 2022
60034421	I	HySolate Latex Dental Dam Green x-heavy Adult (6x6), 36 pcs	March 2022
60034422	I	HySolate Latex Dental Dam Green medium Child (5x5), 364 pcs	March 2022
60034423	I	HySolate Latex Dental Dam Green medium Adult (6x6), 360 pcs	March 2022
60034441	I	HySolate Latex Dental Dam Blue medium Child (5x5), 52 pcs	March 2022
60034442	I	HySolate Latex Dental Dam Blue medium Adult (6x6), 36 pcs	March 2022
60034443	I	HySolate Latex Dental Dam Blue heavy Adult (6x6), 36 pcs	March 2022
60034433	I	HySolate Fiesta Latex Dental Dam thin Adult (6x6), 36 pcs	March 2022
60034434	I	HySolate Fiesta Latex Dental Dam thin Child (5x5), 52 pcs	March 2022
60034435	I	HySolate Fiesta Latex Dental Dam medium Child (5x5), 52 pcs	March 2022
60034436	I	HySolate Fiesta Latex Dental Dam medium Adult (6x6), 36 pcs	March 2022
60034437	I	HySolate Fiesta Latex Dental Dam heavy Child (5x5), 52 pcs	March 2022
60034438	I	HySolate Fiesta Latex Dental Dam heavy Adult (6x6), 36 pcs	March 2022
60034439	I	HySolate Fiesta Latex Dental Dam medium Child (5x5), 364 pcs	March 2022
60034440	I	HySolate Fiesta Latex Dental Dam medium Adult (6x6), 360 pcs	March 2022
60031355	I	HySolate Latex Dental Dam Black pre-printed medium Adult (6x6), 360 pcs	March 2022
60031354	I	HySolate Latex Dental Dam Black pre-printed x-heavy Adult (6x6), 36 pcs	March 2022

Part Number	MDR Class	Description of Finished Product or Item	Introduction Date
60031353	I	HySolate Latex Dental Dam Black pre-printed heavy Adult (6x6), 36 pcs	March 2022
60031352	I	HySolate Latex Dental Dam Black pre-printed medium Adult (6x6), 36 pcs	March 2022
60031351	I	HySolate Latex Dental Dam Black pre-printed thin Adult (6x6), 36 pcs	March 2022
60033844	I	HySolate Latex Dental Dam Black pre-printed thin Adult (6x6), 2 pcs	March 2022
60036125	I	Hysolate Latex Dental Dam Black pre-printed medium Adult (6x6), 2pcs	July 2023
60033845	I	HySolate Latex Dental Dam Green medium Adult (6x6), 2 pcs	March 2022
Dental Dam Kits			
60019066	I	SIMPLE DAM KIT NON-LATEX PREMIUM INST	December 2022
H02778	I	WINGED FIESTA KIT COMPT	December 2022
H02779	I	WINGED FIESTA KIT W/O INST	December 2022
H02790	I	WINGLESS FIESTA KIT COMPLETE	December 2022
H02900	I	SIMPLE DAM KIT	December 2022
Non-Latex Dental Dam			
H00750	I	HYSOLATE FRAMED FLEXI DAM 20 PCS	December 2022
H00751	I	HYSOLATE FRAMED FLEXI DAM SAMPLE	December 2022
H09104	I	Non-Latex, 6" x 6" Medium Teal Dam	December 2022
H09105	I	Non-Latex, 6" x 6" Medium Teal Dam	December 2022
H09106	I	Non-Latex, 6" x 6" Medium Teal Dam	December 2022
H09928	I	HYSOLATE NON LATEX DAM 15 PCS.	December 2022
H09945	I	Flexi-Dam, Non-Latex, 6” x 6” Ready Cut, Medium	December 2022
H09946	I	Flexi-Dam, Non-Latex, 6” x 6” Ready Cut, Medium	December 2022
H09950	I	NL FEXIDAM SAMPLE PURPLE	December 2022
Dental Dam Clamps			
H01048	I	B 1 HySolate TISSUE RETRACTOR	December 2022
H01049	I	B 2 HySolate TISSUE RETRACTOR	December 2022
H01050	I	B 3 HySolate TISSUE RETRACTOR	December 2022
H01051	I	B 4 HySolate TISSUE RETRACTOR	December 2022
H01052	I	B 5 HySolate TISSUE RETRACTOR	December 2022
H01053	I	B 6 HySolate TISSUE RETRACTOR	December 2022
H01054	I	HySolate TISSUE RETRACTORS	December 2022
H02701	I	SYSTEM 9 CLAMP PAK	December 2022
H02703	I	#1 HySolate WINGED CLAMP	December 2022
H02704	I	#4 HySolate WINGED CLAMP	December 2022
H02705	I	#13A HySolate WINGED CLAMP	December 2022
H02706	I	12A HySolate WINGED CLAMP	December 2022
H02757	I	#14A WINGED MOLAR CLAMP	December 2022
H02758	I	#7 WINGED MOLAR CLAMP	December 2022
H02759	I	#8A WINGED MOLAR CLAMP	December 2022
H02760	I	#8 WINGED MOLAR CLAMP	December 2022
H02761	I	#2 WINGED BICUSPID CLAMP	December 2022
H02762	I	#00 WINGED BICUSPID CLAMP	December 2022
H02763	I	#9 WINGED ANTERIOR CLAMP	December 2022
H02764	I	W14A WINGLESS MOLAR CLAMP	December 2022
H02765	I	W7 WINGLESS MOLAR CLAMP	December 2022
H02766	I	W8A WINGLESS MOLAR CLAMP	December 2022
H02767	I	W8 WINGLESS MOLAR CLAMP	December 2022

Part Number	MDR Class	Description of Finished Product or Item	Introduction Date
H02768	I	W2 WINGLESS BICUSPID CLAMP	December 2022
H02769	I	W00 WINGLESS BICUSPID CLAMP	December 2022
H02770	I	W9 WINGLESS ANTERIOR CLAMP	December 2022
H02774	I	W14 WINGLESS MOLAR CLAMP	December 2022
H02775	I	W2A WINGLESS BICUSPID CLAMP	December 2022
H02794	I	#W2 WINGLESS FIESTA CLAMP	December 2022
H02795	I	W2A WINGLESS FIESTA CLAMP	December 2022
H02796	I	#W3 WINGLESS FIESTA CLAMP	December 2022
H02797	I	#W7 WINGLESS FIESTA CLAMP	December 2022
H02798	I	#W8 WINGLESS FIESTA CLAMP	December 2022
H02799	I	#W8A WINGLESS FIESTA CLAMP	December 2022
H02800	I	#W9 WINGLESS FIESTA CLAMP	December 2022
H02801	I	FIESTA 9 COLOR CODED WINGLESS	December 2022
H02802	I	#W14A WINGLESS FIESTA CLAMP	December 2022
H02803	I	#W56 WINGLESS FIESTA CLAMP	December 2022
H03814	I	W3 WINGLESS MOLAR CLAMP	December 2022
H03815	I	W56 WINGLESS MOLAR CLAMP	December 2022
H05688	I	#2A WINGED BICUSPID CLAMP	December 2022
H05689	I	#3 WINGED MOLAR CLAMP	December 2022
H05690	I	#14 WINGED MOLAR CLAMP	December 2022
H07792	I	212 WINGLESS CLAMP	December 2022
H09956	I	FIESTA CC CLAMP ORGANIZER	December 2022
H09957	I	#2 WINGED FIESTA CLAMP	December 2022
H09958	I	#2A WINGED FIESTA CLAMP	December 2022
H09959	I	#4 WINGED FIESTA CLAMP	December 2022
H09960	I	#7 WINGED FIESTA CLAMP	December 2022
H09961	I	#8A WINGED FIESTA CLAMP	December 2022
H09962	I	#9 WINGED FIESTA CLAMP	December 2022
H09963	I	#12A WINGED FIESTA CLAMP	December 2022
H09964	I	#13A WINGED FIESTA CLAMP	December 2022
H09965	I	#14A WINGED FIESTA CLAMP	December 2022
H09966	I	FIESTA 9 COLOR CODED WINGED	December 2022
Wedjets			
H06522	I	WEDJET - SMALL (YELLOW)	December 2022
H06523	I	WEDJET - LARGE (ORANGE)	December 2022
H06524	I	NON-LATEX WEDJET SMALL	December 2022
H06525	I	NON-LATEX WEDJET LARGE	December 2022
H08040	I	WEDJET - EXTRA SMALL (BLUE)	December 2022
Other Accessories			
H01261	I	DENTAL DAM PUNCH	December 2022
H01262	I	DENTAL DAM FORCEPS	December 2022
H01414	I	HySolate 6 FRAME	December 2022
H07082	I	Dam Frame, Metal	December 2022
H07083	I	Dam Frame, Metal	December 2022
H01416	I	HySolate 5 FRAME	December 2022
H00560	I	Dental Dam Frame	December 2022

Part Number	MDR Class	Description of Finished Product or Item	Introduction Date
H01440	I	5 X 5 DAM TEMPLATE	December 2022
H01441	I	6 X 6 DAM TEMPLATE	December 2022
H00841	I	HOLDER SIZE RUBBER DAM NAPKINS	December 2022
H01415	I	FRAME SIZE RUBBER DAM NAPKINS	December 2022