

Declaration of Conformity

for Dental Dam

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Dental Dam
Legal Manufacturer: (Name on Label)	Manufacturera Dental Continental, S.A. de C.V. Calle Industria del Plástico 2113, Fracc. Industrial Zapopan Norte. 45130 Zapopan, Jalisco, México.
Manufacturers SRN:	MX-MF-000043045.
Basic UDI-DI:	75063383DentalDamAD
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Isolates the operative field from one tooth to the entire dental arch. Provides a wide field of view due to its contrasting color, preventing contamination and deglutition of instruments into the oral cavity.
MDR Classification:	Class I [Rule 5]
Notified Body:	Not applicable.
EC Certificate:	Not applicable.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

Name Francisco Javier Ramírez Delgado.

Position Legal Representative

Signed

Date 27/11/2024

Place México

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 22112:2005	Dentistry -- Artificial teeth for dental prostheses
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements

Appendix II – Product Listing/Schedule

1. Nic Tone Rubber Dam

Trade Name	Code	UDI-DI	Color	Thickness	Contents per box	Size	EMDN Code
Nic Tone	144-0012	07506338300513	Blue	Thin	36 sheets	6" x 6"	Q019002
	144-0010	07506338300520	Blue	Thin	36 sheets	5" x 5"	
	144-0014	07506338300537	Blue	Thin	52 sheets	5" x 5"	
	144-0022	07506338300544	Blue	Medium	36 sheets	6" x 6"	
	144-0020	07506338300551	Blue	Medium	36 sheets	5" x 5"	
	144-0024	07506338300568	Blue	Medium	52 sheets	5" x 5"	
	144-0030	07506338300575	Blue	Thick	36 sheets	5" x 5"	
	144-0032	07506338300582	Blue	Thick	36 sheets	6" x 6"	
	144-0034	07506338300599	Blue	Thick	52 sheets	5" x 5"	
	144-0013	07506338300605	Green	Thin	36 sheets	6" x 6"	
	144-0011	07506338300612	Green	Thin	36 sheets	5" x 5"	
	144-0015	07506338300629	Green	Thin	52 sheets	5" x 5"	
	144-0023	07506338300636	Green	Medium	36 sheets	6" x 6"	

144-0021	07506338300643	Green	Medium	36 sheets	5" x 5"
144-0025	07506338300650	Green	Medium	52 sheets	5" x 5"
144-0033	07506338300667	Green	Thick	36 sheets	6" x 6"
144-0031	07506338300674	Green	Thick	36 sheets	5" x 5"
144-0036	07506338300681	Green	Thick	52 sheets	5" x 5"
144-0038	07506338300698	Black	Medium	36 sheets	6" x 6"
144-0037	07506338300704	Black	Thick	36 sheets	6" x 6"
144-0039	07506338322294	Blue	Extra Thick	36 sheets	6" x 6"
144-0040	07506338322140	Black	Thin	36 sheets	6" x 6"
144-0102	07506338322287	Blue	Medium	5 sheets	6" x 6"

2. Easy Dam Rubber Dam

Trade Name	Code	UDI-DI	Color	Thickness	Contents per box	Size	EMDN Code
Easy Dam	144-0300	07506338303347	Blue	Medium	36 sheets	6" x 6"	Q019002

3. Nic Tone Synthetic Dental Dam

Trade Name	Code	UDI-DI	Color	Thickness	Contents per box	Size	EMDN Code
Nic Tone Synthetic Dental Dam	144-0403	07506338315258	Blue	Thin	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0404	07506338315265	Blue	Medium	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0405	07506338315272	Blue	Thick	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0402	07506338315234	Violet	Thin	15 sheets	6" x 6"	Q019002

Nic Tone Synthetic Dental Dam	144-0400	07506338303354	Violet	Medium	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0401	07506338315241	Violet	Thick	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0406	07506338315289	Black	Thin	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0407	07506338315296	Black	Medium	15 sheets	6" x 6"	Q019002
Nic Tone Synthetic Dental Dam	144-0408	07506338315302	Black	Thick	15 sheets	6" x 6"	Q019002

Version History

Version	Compiled by	Date	Description
1.0	Mariana Cacho	March 08, 2022	First issue
2.0	Mariana Cacho	January 31, 2023	New presentations were added of Nic Tone Synthetic Dental Dam.
3.0	Fernando Ayon	November 27, 2024	New presentations of Nic Tone Rubber Dam, Manufacturer SRN, Sole responsibility' statement, and an applicable standard were added