

EU DECLARATION OF CONFORMITY

Legal Manufacturer	<u>Name:</u> Teleflex Medical Inc. <u>Address:</u> 3015 Carrington Mill Blvd Morrisville, NC 27560 USA <u>Single Registration Number (SRN):</u> US-MF-000023660
Authorized Representative	<u>Name:</u> Teleflex Medical <u>Address:</u> IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland <u>Single Registration Number (SRN):</u> IE-AR-000015869
Notified Body	<u>Name:</u> BSI Group the Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands <u>Identification Number:</u> NB 2797

Product Name	Product Classification	Classification Rule	Conformity Assessment Route (s)	EC Certificate(s) No
MAD Nasal Intranasal Mucosal Atomization Device	Class Im	Rule 5	Annex IX	MDR 752387
MADgic Laryngo-Tracheal Mucosal Atomization Device	Class Im	Rule 5	Annex IX	MDR 752387
VaxiNator	Class Is	Rule 5	Annex IX	MDR 752387

Teleflex Medical Inc. declares that the documented product(s) meets the provisions of Regulation (EU) 2017/745. This declaration is made in accordance with Annex IX, Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation, on the basis of the CE Certificate issued by NB 2797, listed below. This declaration is issued under the sole responsibility of Teleflex Medical Inc. and authorizes Teleflex Medical Inc. to affix the CE-marking to the products listed herein.

Intended Purpose:
MAD Nasal and VaxiNator:

For atomizing topical solutions across the naso and oropharyngeal mucous membranes.

MADgic:

Intended for the application of topical anesthetics to the oropharynx and upper airway region.

Basic UDI-DI	Product Name	Product Code	EMDN/CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization Device with 3 mL Syringe	MAD100	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization Device with 1 mL Syringe	MAD110	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization Device with 1 mL Syringe & Vial Adapter	MAD130	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization Device with 3 mL Syringe & Vial Adapter	MAD140	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization	MAD140OS	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V.	16 November 2000

Basic UDI-DI	Product Name	Product Code	EMDN/CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
	Device with 3 mL Oral Syringe & Vial Adapter			Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	
08019020000 00000000009 5KV	MAD Nasal Intranasal Mucosal Atomization Device without Syringe	MAD300	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 6KX	MADgic Laryngo-Tracheal Mucosal Atomization Device with 3 mL Syringe	MAD600	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 6KX	MADgic Laryngo-Tracheal Mucosal Atomization Device without Syringe	MAD700	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000009 6KX	MADgic Pediatric Laryngo-Tracheal Mucosal Atomization Device without Syringe	MAD720	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso, Tecate, B.C, C.P. 21478, Mexico	16 November 2000
08019020000 00000000016 1KH	VaxiNator	VAX300	R9099	Hudson Respiratory Care Tecate S. de R.L. de C.V. Mision Eusebio Kino 1316, Col. Rancho El Descanso,	14 February 2023

Basic UDI-DI	Product Name	Product Code	EMDN/CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
				Tecate, B.C, C.P. 21478, Mexico	

* Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.

Approvals

Name and Title of Approver:	Kelsey Moylan Sr. Regulatory Affairs Manager, Product Management
Signature of Approver:	
Date Approved:	20-Feb-2023
Place of Issue:	3015 Carrington Mill Blvd Morrisville, NC 27560

Change History for Declaration of Conformity:

Revision	Date	Reason for Revision
00	See Agile	Initial release of EU MDR Declaration of Conformity. Change Orders D027470 and D037175.