

Document Number

F1C7002

Revision: E

Effective Date: 07-APR-2021

Page

1 of 3

Declaration of Conformity

EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

	Young Innovations Inc.	
Legal Manufacturer:	Facility SRN#: US-MF-000017796	
Legal Manufacturer Address:	2260 Wendt Street Algonquin, IL. 60102 USA	
Technical File Number:	TF-WA-012	
Declaration of Conformity Number:	DOC-WA-012	
Declaration of Conformity Issue Date:	17-OCT-2022	

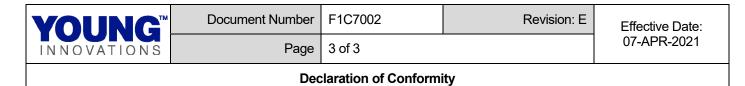
We the manufacturer, Young Innovations Inc, declare that the products named and listed in this Declaration of Conformity meet the provisions of this Council Regulation which apply to them, and the CE mark may be affixed.

Class I

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product Classification:	Class I	
Product Family:	Matrix Bands	
Product Family Intended Use:	Performing dental restorations	
Common Specifications:	Device meets requirements through harmonized standards, see Technical File.	
Sterile:	No	
Measuring Function:	No	
Directive Classification and Rule #	Annex VIII Rule 5	
Notified Body (Name and Identification Number):	N/A	
Conformity Assessment Procedure:	cedure: Annex II-IV	
CE Certificate Number:	N/A	
EU Representative (Name and Address):	Young Microbrush Ireland Ltd. Clogherane, Dungarvan, Co.	

YOUNG	Document Number	F1C7002	Revision: E	Effective Date:	
INNOVATIONS	Page	2 of 3		07-APR-2021	
Declaration of Conformity					
Waterford, X35 VE02, Ireland					
The undersigned authorized person signing Young Innovations Inc for and on behalf of:					
Printed Name and Title	:	Jose Espino, Vice President of Quality & Regulatory Affairs			
Signature:					
Date:		October 17, 2022			



Product Family Item Number Listing

Product Number	Product Description	Basic UDI	
19000	Pro-Matrix Narrow	08434711190000105062224P9	
19001	Pro-Matrix Curve – Narrow	08434711190000105062224P9	
19005	Pro-Matrix Wide	08434711190000105062224P9	
19006	Pro-Matrix Curve – Wide	08434711190000105062224P9	
19022	Pro-Matrix Sample Pack	08434711190000105062224P9	
19024	Pro-Matrix Sample Pack (2 x Wide Curved)	08434711190000105062224P9	