

DECLARATION OF CONFORMITY

Manufacturer: Reinvent Dental Products
Unit 5
16673 148th Avenue,
Spring Lake
MI 49456
USA

SRN: US-MF-000004250

EU Authorised Representative: Eurolink Europe Compliance Limited
25 Herbert Place
Dublin
D02 AY86
Republic of Ireland

SRN: IE-AR-000002852

We the undersigned certify and declare under our sole responsibility that the following apparatus

Conforming Apparatus: NiTin Bands

Device Name and UDI-DI Numbers: See Page 2 below

Risk Class: Class I - MDR Annex VIII Rule 1

**Health Products Regulatory Authority
Registration Reference:** MDROEO202003251341_8

Technical Document Reference No: None

Common Specifications EN ISO 14971:2019 Medical Devices – Application of Risk
Management to Medical Devices
Medical Devices Regulations – Annex I, General
Requirements

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 5 April 2017 on medical devices

Signed:  **Date:** 9 December 2021

Issued: Dublin, Ireland

Michael Morris
Reinvent Dental Products

Device Name	Device Model	Device UDI-DI
Full Curve Metal Matrix Band, Premolar	NTM100	20810038092540
Full Curve Metal Matrix Band, Premolar	NTM100-M	10810038092543
Full Curve Metal Matrix Band with Extension, Premolar	NTM150	20810038092557
Full Curve Metal Matrix Band with Extension, Premolar	NTM150-M	10810038092550
Full Curve Metal Matrix Band, Molar	NTM175	20810038092564
Full Curve Metal Matrix Band, Molar	NTM175-M	10810038092567
Full Curve Metal Matrix Band, Tall Molar	NTM200	20810038092571
Full Curve Metal Matrix Band, Tall Molar	NTM200-M	10810038092574
Full Curve Metal Matrix Band with Extension, Tall Molar	NTM300	20810038092588
Full Curve Metal Matrix Band with Extension, Tall Molar	NTM300-M	10810038092581
Full Curve Matrix Band Kit: 250 Count (50 of Each Size)	NTMK01	00810038096001