# *DECLARATION OF CONFORMITY*

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|---|---|
| ***Manufacturer:*** | Reinvent Dental Products<br>Unit 5<br>16673 148th Avenue,<br>Spring Lake<br>MI 49456<br>USA |
| ***SRN:*** | US-MF-000004250 |
| ***EU Authorised Representative:*** | Eurolink Europe Compliance Limited<br>25 Herbert Place<br>Dublin<br>D02 AY86<br>Republic of Ireland |
| ***SRN:*** | IE-AR-000002852 |

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

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| ***Conforming Apparatus:*** | NiTin Kits |
| ***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<br>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 |
|---|---|---|
| Sectional Matrix Kit: (100) Full Curve Matrices, (100) Wedges, (1) NT400 Ring, (1) NT500 Ring, (1) Ring Placement Forceps, (1) Band Forceps | NT-KMN-01 | 00810038095943 |
| Sectional Matrix Kit: (40) Full Curve Matrices, (40) Wedges, (1) NT500 Ring, (1) Ring Placement Forceps | NT-KMN-35 | 00810038095967 |
| Sectional Matrix Mini Kit: (40) Full Curve Matrices, (40) Wedges, (1) NT400 Ring, (1) NT500 Ring, (1) Ring Placement Forceps | NT-KMN-40 | 00810038095981 |
| Sectional Matrix Trial Kit: (25) Full Curve Matrices, (20) Wedges, (1) NT400 Ring, (1) NT500 Ring, (1) Ring Placement Forceps | NT-MMN-00 | 00810038096018 |