

## 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 Wedge

**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

<b>Device Name</b>	<b>Device Model</b>	<b>Device UDI-DI</b>
Wedge Refill, Small, Blue	NTBL	20810038094209
Wedge Refill, Small, Blue	NTBL-M	10810038094202
Wedge Refill, Large, Green	NTGR	20810038094223
Wedge Refill, Large, Green	NTGR-M	10810038094226
Wedge Assortment Kit: 400 Count (100 of Each Size)	NTK4	00810038095929
Wedge Assortment Kit: 200 Count (50 of Each Size)	NTK4-M	00810038095936
Wedge Refill, Medium, Orange	NTOR	20810038094216
Wedge Refill, Medium, Orange	NTOR-M	10810038094219
Wedge Refill, X-Small, Yellow	NTYL	20810038094193
Wedge Refill, X-Small, Yellow	NTYL-M	10810038094196