

**DECLARATION OF CONFORMITY**

**Manufacturer:** Garrison Dental Solutions  
150 DeWitt Lane  
Spring Lake  
MI 49456  
USA

**SRN:** US-MF-000004112

**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:** G-Wedges

**GMDN:** 45007

**Basic UDI-DI** 081003809WedgesTFZH

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

**Risk Class:** Class I - MDR Annex VIII Rule 1

**Technical Document Reference No:** TFMDRWEDGES

**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

Michael Morris  
Garrison Dental Solutions

**Issued:** Dublin, Ireland

<b>Device Name</b>	<b>Device Model</b>	<b>Device UDI-DI GTIN</b>
G-Wedge™ Blue Single Refill: 100 Count	GSWBL	10810038092932
G-Wedge™ Green Single Refill: 100 Count	GSWGR	10810038092956
G-Wedge™ Orange Single Refill: 100 Count	GSWOR	10810038092949
G-Wedge™ Yellow Single Refill: 100 Count	GSWYL	10810038092925
G-Wedge™ Blue Refill: 300 Count	GWBL	30810038092936
G-Wedge™ Blue Refill: 50 Count	GWBL-E	20810038092939
G-Wedge™ Green Refill: 300 Count	GWGR	30810038092950
G-Wedge™ Green Refill: 50 Count	GWGR-E	20810038092953
G-Wedge™ Kit: 100 Yellow, 100 Blue, 100 Orange, and 100 Green	GWK4	00810038095714
G-Wedge™ Orange Refill: 300 Count	GWOR	30810038092943
G-Wedge™ Orange Refill: 50 Count	GWOR-E	20810038092946
G-Wedge™ Yellow Refill: 300 Count	GWYL	30810038092929
G-Wedge™ Yellow Refill: 50 Count	GWYL-E	20810038092922
Fusion Anterior Wedge Kit: 400 Count	ANK4	00810038090092
Fusion Anterior Wedge Kit: 200 Count	ANK4-M	00810038090108
Fusion Anterior Wedges Yellow: 100 Count	ANYL	10810038090020
Fusion Anterior Wedges Yellow: 50 Count	ANYL-M	20810038090027
Fusion Anterior Wedges Blue: 100 Count	ANBL	10810038090037
Fusion Anterior Wedges Blue: 50 Count	ANBL-M	20810038090034
Fusion Anterior Wedges Orange: 100 Count	ANOR	10810038090044
Fusion Anterior Wedges Orange: 50 Count	ANOR-M	20810038090041
Fusion Anterior Wedges Green: 100 Count	ANGR	10810038090051
Fusion Anterior Wedges Green: 50 Count	ANGR-M	20810038090058
Silver Plus and G-Wedge Starter Kits	SPCGW2-J	00810038096117