

**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:** Composi-Tight 3D Fusion Matrix Products

**GMDN:** 33204

**Basic UDI-DI:** 081003809RingsTFCH

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

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

**Technical Document Reference No:** TFMDRRINGS

**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>
Composi-Tight® 3D Fusion™ Rings Kit: 3 per Package	FXR01	00810038095608
Composi-Tight® 3D Fusion™ Short Rings: 2 per Package	FX400	10810038094523
Composi-Tight® 3D Fusion™ Short Ring: 1 per Package	FX400-1	00810038094526
Composi-Tight® 3D Fusion™ Tall Rings: 2 per Package	FX500	10810038094530
Composi-Tight® 3D Fusion™ Tall Ring: 1 per Package	FX500-1	00810038094533
Composi-Tight® 3D Fusion™ Wide Prep Rings: 2 per Package	FX600	10810038094547
Composi-Tight® 3D Fusion™ Wide Prep Ring: 1 per Package	FX600-1	00810038094540