

**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:** 62764

**Basic UDI-DI:** 081003809BandsTFXZ

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

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

**Technical Document Reference No:** TFMDRBANDS

**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™ Matrix System	FX-HHF-00	00810038095400
Composi-Tight® 3D Fusion™ Matrix System	FX-HHF-40	00810038095417
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-KFF-00	00810038095448
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-KFF-01	00810038095455
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-KFF-04	00810038095462
Composi-Tight® 3D Fusion™ Sectional Matrix System - Main Kit	FX-KFF-10	00810038095479
Composi-Tight® 3D Fusion™ Sectional Matrix System - Plus BFA and TN009	FX-KFF-11	00810038095486
Composi-Tight® 3D Fusion™ Sectional Matrix System - Plus BFA	FX-KFF-14	00810038095493
Composi-Tight® 3D Fusion™ Sectional Matrix System - Short Ring Only	FX-KFF-35	00810038095509
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-KFF-40	00810038095523
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-KFF-50	00810038095547
Composi-Tight® 3D Fusion™ Matrix System	FX-KHF-00	00810038095561
Composi-Tight® 3D Fusion™ Matrix System	FX-KHF-40	00810038095578
Composi-Tight® 3D Fusion™ Sectional Matrix System - Trial Kit	FX-MFF-00	00810038095585
Composi-Tight® 3D Fusion™ Sectional Matrix System - 2 Rings (Short and Tall)	FX-MFF-10	00810038095592
Composi-Tight® 3D Fusion™ Matrix System	FXR-HHF-10	00810038095615
Composi-Tight® 3D Fusion™ Sectional Matrix System	FXR-KFF-10	00810038095622
Composi-Tight® 3D Fusion™ Sectional Matrix System	FXR-KFF-11	00810038095639
Composi-Tight® 3D Fusion™ Sectional Matrix System	FXR-KFF-14	00810038095646
Composi-Tight® 3D Fusion™ Matrix System	FXR-KHF-10	00810038095653