

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: Fusion Matrix Bands

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

Device Name	Device Model	Device UDI-DI GTIN
Composi-Tight® 3D Fusion™ Matrix Bands: 100 Count	FX100	30810038092745
Composi-Tight® 3D Fusion™ Matrix Bands: 10 Count	FX100-E	10810038092741
Composi-Tight® 3D Fusion™ Matrix Bands: 50 Count	FX100-M	20810038092748
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 60 Count	FX150	30810038092752
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 10 Count	FX150-E	10810038092758
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 30 Count	FX150-M	20810038092755
Composi-Tight® 3D Fusion™ Matrix Bands: 100 Count	FX175	30810038092769
Composi-Tight® 3D Fusion™ Matrix Bands: 10 Count	FX175-E	10810038092765
Composi-Tight® 3D Fusion™ Matrix Bands: 50 Count	FX175-M	20810038092762
Composi-Tight® 3D Fusion™ Matrix Bands: 100 Count	FX200	30810038092776
Composi-Tight® 3D Fusion™ Matrix Bands: 50 Count	FX200-M	20810038092779
Composi-Tight® 3D Fusion™ Matrix Bands: 10 Count	FX200-E	10810038092772
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 60 Count	FX300	30810038092783
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 10 Count	FX300-E	10810038092789
Composi-Tight® 3D Fusion™ Matrix Bands with Extension: 30 Count	FX300-M	20810038092786
Composi-Tight® 3D Fusion™ Matrix Band Kit: 420 Count	FXB01	00810038095271
Composi-Tight® 3D Fusion™ Matrix Band Kit: 210 Count	FXB02	00810038095288
Composi-Tight® 3D Fusion™ Matrix Band Sample Kit: 25 Count	FXBS01	00810038095295
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-DFF-0A	00810038095301
Composi-Tight® 3D Fusion™ Sectional Matrix System	FX-DFF-0B	00810038095318
Fusion Anterior Matrix Bands Short: 100 Count	AN100	10810038090006
Fusion Anterior Matrix Bands Short: 50 Count	AN100-M	20810038090003
Fusion Anterior Matrix Bands Tall: 100 Count	AN200	10810038090013
Fusion Anterior Matrix Bands Tall: 50 Count	AN200-M	20810038090010
Fusion Anterior Matrix System	ANK01	00810038090061
Fusion Anterior Matrix System	ANK02	00810038090078
Fusion Anterior Trial Kit	ANS01	00810038090085