

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:

TFMDR BANDS

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: 3 October 2022



Issued: Dublin, Ireland

Michael Morris
Garrison Dental Solutions

Device Name	Device Model	Device UDI-DI GTIN
Composi-Tight® 3D Fusion™ Matrix System	FX-HHF-00	00810038095400
Composi-Tight® 3D Fusion™ Matrix System	FX-HHF-40	00810038095417
Composi-Tight® 3D Fusion™ Matrix System	FX-HHF-00-VM	00810038090467
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™ Sectional Matrix System	FX-KFF-00-VM	00810038090450
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