



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: 30 December 2021

A handwritten signature in blue ink, appearing to read "Michael Morris".

Issued: Dublin, Ireland

Michael Morris
Garrison Dental Solutions

Device Name	Device Model	Device UDI-DI GTIN
Composi-Tight® 3D Fusion™ Firm Intro Kit	FX-HHF-50	00810038090221