

**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 and 3DX 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 Thin Tine G-Rings: 3 Per Package	3D400	20810038093677
Composi-Tight® 3D Thin Tine G-Ring Refill: 2 Per Package	3D400-M	10810038093670
Composi-Tight® 3D Thin Tine G-Ring: 1 Per Package	3D400-1	00810038093673
Composi-Tight® 3D Soft Face Rings: 2 Per Package	3D500	10810038093687
Composi-Tight® 3D Soft Face Ring: 1 Per Package	3D500-1	00810038093680
Composi-Tight® 3D Clear Soft Face Rings: 2 Per Package	3D600	10810038093694
Composi-Tight® 3D Clear Soft Face Ring: 1 Per Package	3D600-1	00810038093697
Composi-Tight® 3DXR Rings: 2 per Package	3DXR	10810038093700
Composi-Tight® 3DXR Ring: 1 per Package	3DXR-1	00810038093703