Garrison®

# EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices

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|---|---|
| **Document Number:** | DOC-EU-RINGS |
| **Manufacturer** | Garrison Dental Solutions, LLC<br>150 DeWitt Lane<br>Spring Lake<br>MI 49456<br>USA |
| **SRN:** | US-MF-000004112 |
| **EU Authorized Representative** | **Eurolink Europe Compliance Limited**<br>25 Herbert Place<br>Dublin D02 AY86<br>Republic of Ireland |
| **SRN:** | IE-AR-000002852 |

We the undersigned certify and declare under our sole responsibility that the following device family:

| | |
|---|---|
| **Device Family Name:** | Matrix Rings Family |
| **Technical Document Reference No:** | TFMDRRINGS |
| **Basic UDI-DI** | 0081003809RingsTFCH |
| **GMDN Code(s) and Description(s):** | 33204 - Dental matrix band retainer |
| **EMDN Code(s) and Description(s):** | Q010399 - SURGICAL DENTAL DEVICES - OTHER |
| **Risk Classification** | Class I - Annex VIII Rule 5 |
| **Conformity Assessment Route** | MDR Article 52(7) for Class I devices |
| **Applicable Standards & Legislation** | ISO 13485:2016+A11:2021<br>ISO 14971:2019+A11:2021<br>ISO/TR 24971:2020<br>ISO 15223-1:2021<br>ISO 20417:2021<br>Regulation (EU) 2017/745 |
| **Intended Purpose:** | The Matrix Rings Family is intended for use by dental professionals as part of a sectional matrix system during restorative dental procedures. The rings provide tooth separation and matrix band adaptation to support the creation of proper proximal contacts and anatomically accurate restorations. |

**Declaration**

Garrison Dental Solutions, LLC declares under its sole responsibility that the devices identified within Technical Documentation File TFMDRRINGS and associated with Basic UDI-DI 0081003809RingsTFCH comply with the applicable requirements of Regulation (EU) 2017/745 on Medical Devices, including the applicable General Safety and Performance Requirements of Annex I.

The devices covered by this Declaration are designed, manufactured, controlled, and distributed under the Garrison Dental Solutions Quality Management System certified to ISO 13485:2016.



150 DeWitt Lane, Spring Lake, MI 49456-1921 USA 616.842.2244 info@garrisondental.com **garrisondental.com**

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| SKU | Description | GMDN | EMDN |
|---|---|---|---|
| 3D500 | Composi-Tight 3D Soft Face Rings: 2 per package | 33204 | Q010399 |
| 3D500-1 | Composi-Tight 3D Soft Face Ring: 1 per package | 33204 | Q010399 |
| 3DXR | Composi-Tight 3DXR Rings: 2 per package | 33204 | Q010399 |
| 3DXR-1 | Composi-Tight 3DXR Ring: 1 per package | 33204 | Q010399 |
| AU400 | Composi-Tight Gold G-Rings with standard length tines: 3 Count | 33204 | Q010399 |
| AU500 | Composi-Tight Gold G-Rings with long length tines: 3 Count | 33204 | Q010399 |
| FX400 | Composi-Tight 3D Fusion Short Rings: 2 per package | 33204 | Q010399 |
| FX400-1 | Composi-Tight 3D Fusion Short Ring: 1 per package | 33204 | Q010399 |
| FX500 | Composi-Tight 3D Fusion Tall Rings: 2 per package | 33204 | Q010399 |
| FX500-1 | Composi-Tight 3D Fusion Tall Ring: 1 per package | 33204 | Q010399 |
| FX600 | Composi-Tight 3D Fusion Wide Prep Rings: 2 per package | 33204 | Q010399 |
| FX600-1 | Composi-Tight 3D Fusion Wide Prep Ring: 1 per package | 33204 | Q010399 |
| FXR01 | Composi-Tight 3D Fusion Rings Kit; 3 per package | 33204 | Q010399 |
| G100 | Composi-Tight Original G-Rings with standard length tines: 3 per package | 33204 | Q010399 |
| G200 | Composi-Tight Original G-Rings with long length tines | 33204 | Q010399 |
| NTG400 | NiTin Garrison Long Rings: 2 per package | 33204 | Q010399 |
| NTG400-1 | NiTin Garrison Long Rings: 1 per package | 33204 | Q010399 |
| NTG500 | NiTin Garrison Standard Rings: 2 per package | 33204 | Q010399 |
| NTG500-1 | NiTin Garrison Standard Rings: 1 per package | 33204 | Q010399 |
| SGR01 | Strata-G™ Rings Kit: 3 per package | 33204 | Q010399 |
| SG400 | Strata-G™ Short Ring: 2 per package | 33204 | Q010399 |
| SG400-1 | Strata-G™ Short Ring: 1 per package | 33204 | Q010399 |
| SG500 | Strata-G™ Tall Ring: 2 per package | 33204 | Q010399 |
| SG500-1 | Strata-G™ Tall Ring: 1 per package | 33204 | Q010399 |
| SG600 | Strata-G™ Wide Prep Ring: 2 per package | 33204 | Q010399 |
| SG600-1 | Strata-G™ Wide Prep Ring: 1 per package | 33204 | Q010399 |
| NT400 | NiTin Molar (Long) Rings: 2 per package | 33204 | Q010399 |
| NT400-1 | NiTin Molar (Long) Rings: 1 per package | 33204 | Q010399 |
| NT500 | NiTin Premolar (Standard) Rings: 2 per package | 33204 | Q010399 |
| NT500-1 | NiTin Premolar (Standard) Rings: 1 per package | 33204 | Q010399 |
| QR01 | Quad Rings Kit | 33204 | Q010399 |
| Q400 | Quad Short Ring: 2 count | 33204 | Q010399 |
| Q500 | Quad Tall Ring: 2 count | 33204 | Q010399 |
| Q400L-1 | Quad Short Ring: 1 left count | 33204 | Q010399 |
| Q400R-1 | Quad Short Ring: 1 right count | 33204 | Q010399 |
| Q500L-1 | Quad Tall Ring: 1 left count | 33204 | Q010399 |
| Q500R-1 | Quad Tall Ring: 1 right count | 33204 | Q010399 |

| Revision | Date | Description |
|---|---|---|
| A | 2026-08-03 | Initial release. New EU Declaration of Conformity for Ring family. |

**Place of Issue:** Spring Lake, Michigan, USA
**Date of Issue:** 03 August 2026

**Signed,**

David Snellen

Digitally signed by David Snellen
DN: CN=David Snellen, O=Garrison Dental Solutions, E=dsnellen@garrisondental.com
Reason: I attest to the accuracy and integrity of this document
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**David Snellen**
Quality & Regulatory Manager
Garrison Dental Solutions, LLC
150 DeWitt Lane, Spring Lake, MI 49456 USA



150 DeWitt Lane, Spring Lake, MI 49456-1921 USA 616.842.2244 info@garrisondental.com **garrisondental.com**