Garrison®

EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices

Document Number:	DOC-EU-BANDS
Manufacturer	Garrison Dental Solutions, LLC 150 DeWitt Lane Spring Lake MI 49456 USA
SRN:	US-MF-000004112
EU Authorized 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 device family:

Device Family Name:	Matrix Bands Family
Technical Document Reference No:	TFMDRBANDS
Basic UDI-DI	081003809BandsTFXZ
GMDN Code(s) and Description(s):	38786 - Matrix band, dental 62764 - Dental matrix band kit
EMDN Code(s) and Description(s):	Q01010401 - PAPER AND GUTTA-PERCHA TIPS, MATRICES AND WEDGES FOR DENTISTRY Q01010199 - DENTAL RESTORATION DEVICES - OTHER
Risk Classification	Class I – Annex VIII Rule 1 and Rule 5
Conformity Assessment Route	MDR Article 52(7) for Class I devices
Applicable Standards & Legislation	ISO 13485:2016+A11:2021 ISO 14971:2019+A11:2021 ISO/TR 24971:2020 ISO 15223-1:2021 ISO 20417:2021 Regulation (EU) 2017/745
Intended Purpose:	The Matrix Bands Family is intended for use by dental professionals as part of a matrix system during restorative dental procedures. The bands assist in the placement and contouring of restorative materials to provide proper tooth form, proximal contact, gingival adaptation, and restoration anatomy while minimizing damage to adjacent teeth and tissues.

Declaration

Garrison Dental Solutions, LLC declares under its sole responsibility that the devices identified within Technical Documentation File TFMDRBANDS and associated with Basic UDI-DI 081003809BandsTFXZ 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

Garrison®

SKU	Description	GMDN	EMDN
3D-KFF-00	Composi-Tight 3DXR Sectional Matrix Kit	62764	Q01010199
3D-KMW-00	Composi-Tight 3DXR Complete Sectional Matrix Kit	62764	Q01010199
AN100	Fusion Anterior Matrix Bands Short: 100	38786	Q01010401
AN100-M	Fusion Anterior Matrix Bands Short: 50	38786	Q01010401
AN200	Fusion Anterior Matrix Bands Tall: 100	38786	Q01010401
AN200-M	Fusion Anterior Matrix Bands Tall: 50	38786	Q01010401
ANK01	Fusion Anterior Matrix System	62764	Q01010199
ANK02	Fusion Anterior Matrix System	62764	Q01010199
AUK2	Composi-Tight Gold Sectional Matrix Kit with Ring Placement Forceps	62764	Q01010199
AU050	Composi-Tight Gold pedodontic matrix with extension	38786	Q01010401
AU050-M	Composi-Tight Gold pedodontic matrix bands	38786	Q01010401
AU100	Composi-Tight Gold bicuspid matrix band: 100 count	38786	Q01010401
AU100-M	Composi-Tight Gold bicuspid matrix band: 50 count	38786	Q01010401
AU150	Composi-Tight Gold bicuspid matrix band with extension: 50 count	38786	Q01010401
AU150-M	Composi-Tight Gold bicuspid matrix band with extension: 25 count	38786	Q01010401
AU200	Composi-Tight Gold molar matrix band: 100 count	38786	Q01010401
AU200-M	Composi-Tight Gold molar matrix band: 50 count	38786	Q01010401
AU300	Composi-Tight Gold molar matrix band with extension: 50 count	38786	Q01010401
AU300-M	Composi-Tight Gold molar matrix band with extension: 25 count	38786	Q01010401
B050	Composi-Tight Original pedodontic matrix band with extension: 50 count	38786	Q01010401
B050-M	Composi-Tight Original pedodontic matrix band with extension: 25 count	38786	Q01010401
B100	Composi-Tight Original bicuspid matrix band: 100 count	38786	Q01010401
B100-M	Composi-Tight Original bicuspid matrix band: 50 count	38786	Q01010401
B150	Composi-Tight Original bicuspid matrix band with extension: 50 count	38786	Q01010401
B150-M	Composi-Tight Original bicuspid matrix band with extension: 25 count	38786	Q01010401
B200	Composi-Tight Original molar matrix band: 100 count	38786	Q01010401
B200-M	Composi-Tight Original molar matrix band: 50 count	38786	Q01010401
B300	Composi-Tight Original molar matrix with extension: 50 count	38786	Q01010401
B300-M	Composi-Tight Original molar matrix with extension: 25 count	38786	Q01010401
FX100	Composi-Tight 3D Fusion Matrix Bands: 100 Count	38786	Q01010401
FX100-M	Composi-Tight 3D Fusion Matrix Bands: 50 Count	38786	Q01010401
FX150	Composi-Tight 3D Fusion Matrix Bands with Extension: 60 Count	38786	Q01010401
FX150-M	Composi-Tight 3D Fusion Matrix Bands with Extension: 30 Count	38786	Q01010401
FX175	Composi-Tight 3D Fusion Matrix Bands: 100 Count	38786	Q01010401
FX175-M	Composi-Tight 3D Fusion Matrix Bands: 50 Count	38786	Q01010401
FX200	Composi-Tight 3D Fusion Matrix Bands: 100 Count	38786	Q01010401
FX200-M	Composi-Tight 3D Fusion Matrix Bands: 50 Count	38786	Q01010401
FX300	Composi-Tight 3D Fusion Matrix Bands with Extension: 60 Count	38786	Q01010401
FX300-M	Composi-Tight 3D Fusion Matrix Bands with Extension: 30 Count	38786	Q01010401
FXB01	Composi-Tight 3D Fusion Matrix Band Kit: 420 Count	38786	Q01010401
FXB02	Composi-Tight 3D Fusion Matrix Band Kit: 210 Count	38786	Q01010401
FXBS01	Composi-Tight 3D Fusion Matrix Band Sample Kit: 25 Count	38786	Q01010401
FXH100	Composi-Tight 3D Fusion Firm Matrix Band: 100 Count	38786	Q01010401
FXH100-M	Composi-Tight 3D Fusion Firm Matrix Band: 50 Count	38786	Q01010401
FXH150	Composi-Tight 3D Fusion Firm Matrix Bands: 100 Count	38786	Q01010401
FXH150-M	Composi-Tight 3D Fusion Firm Matrix Band: 50 Count	38786	Q01010401
FXH175	Composi-Tight 3D Fusion Firm Matrix Band: 100 Count	38786	Q01010401

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

Garrison®

SKU	Description	GMDN	EMDN
FXH175-M	Composi-Tight 3D Fusion Firm Matrix Band: 50 Count	38786	Q01010401
FXH200	Composi-Tight 3D Fusion Firm Matrix Band: 100 Count	38786	Q01010401
FXH200-M	Composi-Tight 3D Fusion Firm Matrix Band: 50 Count	38786	Q01010401
FXH300	Composi-Tight 3D Fusion Firm Matrix Band: 100 Count	38786	Q01010401
FXH300-M	Composi-Tight 3D Fusion Firm Matrix Band: 50 Count	38786	Q01010401
FXHB04	Composi-Tight 3D Fusion Firm Matrix Bands Kit: 300 count	38786	Q01010401
FXHB05	Composi-Tight 3D Fusion Firm Matrix Bands Mini Kit: 150 count	38786	Q01010401
FXHBS02	Composi-Tight 3D Fusion Firm Matrix Bands Sample Kit: 15 count	38786	Q01010401
FXHBS03	Composi-Tight 3D Fusion Firm Matrix Bands Sample Kit	38786	Q01010401
FX-HHF-00	Composi-Tight 3D Fusion Matrix System	62764	Q01010199
FX-HHF-00-VM	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-HHF-40	Composi-Tight 3D Fusion Matrix System	62764	Q01010199
FX-HHF-50	Composi-Tight 3D Fusion Matrix System	62764	Q01010199
FX-KFF-00	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-KFF-00-VM	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-KFF-01	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-KFF-04	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-KFF-35	Composi-Tight 3D Fusion Sectional Matrix System- Short ring only	62764	Q01010199
FX-KFF-40	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
FX-KFF-50	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
K102	Composi-Tight Sectional Matrix Kit with Ring Placement Forceps	62764	Q01010199
M050	Composi-Tight pedodontic matrix with extension: 50 count	38786	Q01010401
M050-M	Composi-Tight pedodontic matrix with extension: 25 count	38786	Q01010401
M100	Composi-Tight bicuspid matrix: 100 count	38786	Q01010401
M100-M	Composi-Tight bicuspid matrix: 50 count	38786	Q01010401
M150	Composi-Tight bicuspid matrix with extension: 50 count	38786	Q01010401
M150-M	Composi-Tight bicuspid matrix with extension: 25 count	38786	Q01010401
M175	Composi-Tight 5.5mm molar matrix: 100 count	38786	Q01010401
M175-M	Composi-Tight 5.5mm molar matrix: 50 count	38786	Q01010401
M200	Composi-Tight molar matrix: 100 count	38786	Q01010401
M200-M	Composi-Tight molar matrix: 50 count	38786	Q01010401
M300	Composi-Tight molar matrix with extension: 50 count	38786	Q01010401
M300-M	Composi-Tight molar matrix with extension: 25 count	38786	Q01010401
NTG100	NiTin Garrison Matrix Premolar, 4.0mm (w/ext 4.4mm): 50 bands	38786	Q01010401
NTG100-M	NiTin Garrison Matrix Premolar, 4.0mm (w/ext 4.4mm): 25 bands	38786	Q01010401
NTG150	NiTin Garrison Matrix Premolar, 4.1mm (w/ext 6.0mm): 50 bands	38786	Q01010401
NTG150-M	NiTin Garrison Matrix Premolar, 4.1mm (w/ext 6.0mm): 25 bands	38786	Q01010401
NTG175	NiTin Garrison Matrix Molar, 5.0mm (w/ext 5.6mm) 50 bands	38786	Q01010401
NTG175-M	NiTin Garrison Matrix Molar, 5.0mm (w/ext 5.6mm) 25 bands	38786	Q01010401
NTG200	NiTin Garrison Matrix Molar, 5.5mm (w/ext 6.6mm): 50 bands	38786	Q01010401
NTG200-M	NiTin Garrison Matrix Tall Molar, 5.5mm (w/ext 6.6mm): 25 bands	38786	Q01010401
NTG300	NiTin Garrison Matrix Tall Molar, 6.0mm (w/ext 8.7mm): 50 bands	38786	Q01010401
NTG300-M	NiTin Garrison Matrix Tall Molar, 6.0mm (w/ext 8.7mm): 25 bands	38786	Q01010401
NTGK01	NiTin Garrison Matrix Bands Kit: 250 bands	38786	Q01010401
NTG-KMG-01	NiTin Garrison Sectional Matrix Kit	62764	Q01010199
NTG-KMG-40	NiTin Garrison Sectional Matrix Mini Kit	62764	Q01010199
NTG-MMG-00	NiTin Garrision Sectional Matrix Trial Kit	62764	Q01010199
SGBS01	Strata-G™ Matrix Band Trial Kit	38786	Q01010401
SG-KSH-10	Strata-G™ Sectional Matrix System Professional Kit	62764	Q01010199
SG-KSH-11	Strata-G™ Sectional Matrix System Intro Kit	62764	Q01010199
SG-KSH-14	Strata-G™ Sectional Matrix System Deluxe Kit	62764	Q01010199
SG-KS-00	Strata-G™ Sectional Matrix System Intro Kit	62764	Q01010199

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

Garrison®

SKU	Description	GMDN	EMDN
SG-KS-35	Strata-G™ Sectional Matrix System Trial Kit	62764	Q01010199
SG-KS-40	Strata-G™ Sectional Matrix System Standard Kit	62764	Q01010199
SG-KS-50	Strata-G™ Sectional Matrix System Basic Kit	62764	Q01010199
SG-KH-00	Strata-G™ Firm Sectional Matrix System Intro Kit	62764	Q01010199
SG-KH-40	Strata-G™ Firm Sectional Matrix System Standard Kit	62764	Q01010199
SGB01	Strata-G™ Matrix Band Kit: 400 Count	38786	Q01010401
SGB02	Strata-G™ Matrix Band Kit: 200 Count	38786	Q01010401
SG050	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG050-M	Strata-G™ Matrix Bands: 50 Count	38786	Q01010401
SG100	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG100-M	Strata-G™ Matrix Bands: 50 Count	38786	Q01010401
SG175	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG175-M	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG200	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG200-M	Strata-G™ Matrix Bands: 50 Count	38786	Q01010401
SG300	Strata-G™ Matrix Bands: 100 Count	38786	Q01010401
SG300-M	Strata-G™ Matrix Bands: 50 Count	38786	Q01010401
SBSP1	Slick Bands Trial Pack: 35 count	38786	Q01010401
SM100	Slick Bands bicuspid matrix Grey: 100 count	38786	Q01010401
SM100-E	Slick Bands bicuspid matrix Grey: 25 count	38786	Q01010401
SM100-M	Slick Bands bicuspid matrix Grey: 50 count	38786	Q01010401
SM150	Slick Bands bicuspid matrix with extension Red: 60 count	38786	Q01010401
SM150-E	Slick Bands bicuspid matrix with extension Red: 15 count	38786	Q01010401
SM150-M	Slick Bands bicuspid matrix with extension Red: 30 count	38786	Q01010401
SM175	Slick Bands 5.5mm molar matrix Purple: 100 count	38786	Q01010401
SM175-E	Slick Bands 5.5mm molar matrix Purple: 25 count	38786	Q01010401
SM175-M	Slick Bands 5.5mm molar matrix Purple: 50 count	38786	Q01010401
SM200	Slick Bands molar matrix Green: 100 count	38786	Q01010401
SM200-E	Slick Bands molar matrix Green: 25 count	38786	Q01010401
SM200-M	Slick Bands molar matrix Green: 50 count	38786	Q01010401
SM300	Slick Bands molar matrix with extension Blue: 60 count	38786	Q01010401
SM300-E	Slick Bands molar matrix with extension Blue: 15 count	38786	Q01010401
SM300-M	Slick Bands molar matrix with extension Blue: 30 count	38786	Q01010401
SMBRP1	Slick Bands Multi-Band Refill Kit: 420 count	38786	Q01010401
SMT050D10	#13 Pedo Non Stick Matrix Band-Dead Soft 100/Pack	38786	Q01010401
SMT050D10-M	#13 Pedo Non Stick Matrix Band-Dead Soft 50/Pack	38786	Q01010401
SMT050H10	#13 Pedo Non-Stick Matrix Band-Regular 100/Pack	38786	Q01010401
SMT050H10-M	#13 Pedo Non-Stick Matrix Band-Regular 50/Pack	38786	Q01010401
SMT200D10	Slick Bands #1 Universal Dead Soft Tofflemire Matrix 100/pack- Green	38786	Q01010401
SMT200D10-M	Slick Bands #1 Universal Dead Soft Tofflemire Matrix 50/pack- Green	38786	Q01010401
SMT200H10	Slick Bands #1 Universal Regular Tofflemire Matrix 100/pack- Gray	38786	Q01010401
SMT200H10-M	Slick Bands #1 Universal Regular Tofflemire Matrix 50/pack- Gray	38786	Q01010401
SMT300D10	#2 Subgingival Non-Stick Matrix Band-Dead Soft 100/Pack	38786	Q01010401
SMT300D10-M	#2 Subgingival Non-Stick Matrix Band-Dead Soft 50/Pack	38786	Q01010401
SMT300H10	#2 Subgingival Non-Stick Matrix Bands-Regular 100/Pack	38786	Q01010401
SMT300H10-M	#2 Subgingival Non-Stick Matrix Bands-Regular 50/Pack	38786	Q01010401
SMT400D10	Right-Curve Tofflemire Matrix Bands Dead-Soft 100/Package	38786	Q01010401
SMT400D10-M	Right-Curve Tofflemire Matrix Bands Dead-Soft 50/Package	38786	Q01010401
SMT400H10	Right-Curve Tofflemire Matrix Bands Regular 100/Package	38786	Q01010401
SMT400H10-M	Right-Curve Tofflemire Matrix Bands Regular 50/Package	38786	Q01010401

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

Garrison®

SKU	Description	GMDN	EMDN
SMT500H10	Slick Bands Tofflemire Margin Elevation Matrix- 100/pack	38786	Q01010401
SMT500H10-M	Slick Bands Margin Elevation Matrix- 50/pack	38786	Q01010401
SMT500S01	Slick Bands Margin Elevation Matrix- 20/pack- SAMPLE PACK	38786	Q01010401
SMTK06	Slick Bands Tofflemire Kit with G-Wedges and PerForm Instruments	62764	Q01010199
SXR100	Slick Bands XR bicuspid matrix Gray: 100 count	38786	Q01010401
SXR100-M	Slick Bands XR bicuspid matrix Gray: 50 count	38786	Q01010401
SXR150	Slick Bands XR bicuspid matrix with extension Red: 60 Count	38786	Q01010401
SXR150-M	Slick Bands XR bicuspid matrix with extension Red: 30 Count	38786	Q01010401
SXR175	Slick Bands XR 5.5mm molar matrix Purple: 100 count	38786	Q01010401
SXR175-M	Slick Bands XR 5.5mm molar matrix Purple: 50 count	38786	Q01010401
SXR200	Slick Bands XR molar matrix Green: 100 count	38786	Q01010401
SXR200-M	Slick Bands XR molar matrix Green: 50 count	38786	Q01010401
SXR300	Slick Bands XR molar matrix with extension Blue: 60 Count	38786	Q01010401
SXR300-M	Slick Bands XR molar matrix with extension Blue: 30 count	38786	Q01010401
SXRB01	Slick Bands XR Trial Pack: 25 Count	38786	Q01010401
SXRB02	Slick Bands XR Band Refill Kit: 420 count	38786	Q01010401
UN30	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
UN31	Composi-Tight 3D Fusion Sectional Matrix System	62764	Q01010199
VS01	BlueView VariStrip contoured anterior matrix: 100 count	38786	Q01010401
VS02	BlueView VariStrip contoured anterior matrix: 50 count	38786	Q01010401
VS03	BlueView VariStrip contoured anterior matrix Trial Pack: 20 count	38786	Q01010401
VS04	VariStrip Sample Pack: 4 Per Package	38786	Q01010401
NT-KMN-01	NiTin Sectional Matrix Kit with Full Curve Metal Bands	62764	Q01010199
NT-KMN-35	NiTin Sectional Matrix Mini Kit	62764	Q01010199
NT-KMN-40	NiTin Sectional Matrix Mini Kit	62764	Q01010199
NTM100	NiTin Metal Full Curve Matrix Bands Premolar, 4.0 mm (w/ext 4.4mm): 50 bands	38786	Q01010401
NTM100-M	NiTin Metal Full Curve Matrix Bands Premolar, 4.0 mm (w/ext 4.4mm) 25 bands	38786	Q01010401
NTM150	NiTin Metal Full Curve Matrix Bands w/Ext Premolar, 4.1 mm (w/ext 6.0mm 50 bands)	38786	Q01010401
NTM150-M	NiTin Metal Full Curve Matrix Bands wi/Ext 6.6mm Premolar, 4.1 mm (25 Bands)	38786	Q01010401
NTM175	NiTin Metal Full Curve Matrix Bands Molar, 5.0 mm (w/ext 5.6mm 50 bands)	38786	Q01010401
NTM175-M	NiTin Metal Full Curve Matrix Bands Molar, 5.0 mm (w/ext 5.6mm 25 bands)	38786	Q01010401
NTM200	NiTin Metal Full Curve Matrix Bands Tall Molar, 5.4 mm (w/ext 6.6 mm 50 bands)	38786	Q01010401
NTM200-M	NiTin Metal Full Curve Matrix Bands Tall Molar, 5.4 mm (w/ext 6.6mm 25 bands)	38786	Q01010401
NTM300	NiTin Metal Full Curve Matrix Bands with Extension Tall Molar, 6.0mm (50mm)	38786	Q01010401
NTM300-M	NiTin Metal Full Curve Matrix Bands with Extension Tall Molar, 6.0 mm (25 bands)	38786	Q01010401
NTMK01	NiTin Matrix Band Kit: 250 bands	38786	Q01010401
NT-MMN-00	NiTin Sectional Matrix Trial Kit	62764	Q01010199
Q-KHF-00-R	Quad Sectional Matrix System Refill Kit	62764	Q01010199
Q-KHF-00	Quad Sectional Matrix System Intro Kit	62764	Q01010199
Q-KHF-10	Quad Sectional Matrix System Intro Kit	62764	Q01010199
Q-KHF-11	Quad Sectional Matrix System Professional Kit	62764	Q01010199
Q-KHF-14	Quad Sectional Matrix System Deluxe Kit	62764	Q01010199

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

SKU	Description	GMDN	EMDN
Q-KHF-40	Quad Sectional Matrix System Standard Kit	62764	Q01010199
Q-KH-00	Quad Sectional Matrix System Intro Kit	62764	Q01010199

Revision	Date	Description
A	2026-08-03	Initial release. New EU Declaration of Conformity for Matrix Band 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
Location:
Date: 2026.08.11 13:48:00-04'00'
Foxit PDF Editor Version: 2026.1.2



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**