Garrison®

EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices

Document Number:	DOC-EU-WEDGES
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:	The Wedges Family
Technical Document Reference No:	TFMDRWEDGES
Basic UDI-DI	081003809WedgesTFZH
GMDN Code(s) and Description(s):	45007 - Dental wedge, single-use
EMDN Code(s) and Description(s):	Q01010401 - PAPER AND GUTTA-PERCHA TIPS, MATRICES AND WEDGES FOR DENTISTRY
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 ISO 14971:2019+A11:2021 ISO/TR 24971:2020 ISO 15223-1:2021 ISO 20417:2021 Regulation (EU) 2017/745
Intended Purpose:	The Wedges Family is intended for use by dental professionals as part of a matrix system during restorative dental procedures. The wedges assist matrix band adaptation, tooth separation, gingival margin sealing, and restoration placement to support proper 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 TFMDRWEDGES and associated with Basic UDI-DI 081003809WedgesTFZH 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
ANYL	Fusion Anterior Wedges Yellow: 100 Count	45007	Q01010401
ANYL-M	Fusion Anterior Wedges Yellow: 50 Count	45007	Q01010401
ANBL	Fusion Anterior Wedges Blue: 100 Count	45007	Q01010401
ANBL-M	Fusion Anterior Wedges Blue: 50 Count	45007	Q01010401
ANOR	Fusion Anterior Wedges Orange: 100 Count	45007	Q01010401
ANOR-M	Fusion Anterior Wedges Orange: 50 Count	45007	Q01010401
ANGR	Fusion Anterior Wedges Green: 100 Count	45007	Q01010401
ANGR-M	Fusion Anterior Wedges Green: 50 Count	45007	Q01010401
ANK4	Fusion Anterior Wedge Kit: 400 Count	45007	Q01010401
ANK4-M	Fusion Anterior Wedge Kit: 200 Count	45007	Q01010401
FXBL	Composi-Tight 3D Fusion Wedge Blue Refill: 100 Count	45007	Q01010401
FXBL-M	Composi-Tight 3D Fusion Wedge Blue Refill: 50 Count	45007	Q01010401
FXGR	Composi-Tight 3D Fusion Wedge Green Refill: 100 Count	45007	Q01010401
FXGR-M	Composi-Tight 3D Fusion Wedge Green Refill: 50 Count	45007	Q01010401
FXK4	Composi-Tight 3D Fusion Wedge Kit: 400 count	45007	Q01010401
FXK4-M	Composi-Tight 3D Fusion Wedge Kit: 200 count	45007	Q01010401
FXOR	Composi-Tight 3D Fusion Wedge Orange Refill: 100 Count	45007	Q01010401
FXOR-M	Composi-Tight 3D Fusion Wedge Orange Refill: 50 Count	45007	Q01010401
FXS01	Composi-Tight 3D Fusion Wedge Kit: 60 count	45007	Q01010401
FXYL	Composi-Tight 3D Fusion Wedge Yellow Refill: 100 Count	45007	Q01010401
FXYL-M	Composi-Tight 3D Fusion Wedge Yellow Refill: 50 Count	45007	Q01010401
SGS01	Strata-G™ Wedge Trial Kit	45007	Q01010401
SGK4	Strata-G™ Wedge Kit: 400	45007	Q01010401
SGK4-M	Strata-G™ Wedge Kit: 200	45007	Q01010401
SGYL	Strata-G™ Wedge Yellow Refill: 100 Count	45007	Q01010401
SGYL-M	Strata-G™ Wedge Yellow Refill: 50 Count	45007	Q01010401
SGBL	Strata-G™ Wedge Blue Refill: 100 Count	45007	Q01010401
SGBL-M	Strata-G™ Wedge Blue Refill: 50 Count	45007	Q01010401
SGOR	Strata-G™ Wedge Orange Refill: 100 Count	45007	Q01010401
SGOR-M	Strata-G™ Wedge Orange Refill: 50 Count	45007	Q01010401
SGGR	Strata-G™ Wedge Green Refill: 100 Count	45007	Q01010401
SGGR-M	Strata-G™ Wedge Green Refill: 50 Count	45007	Q01010401
NTBL	NiTin Wedge Small Refill: 100 count	45007	Q01010401
NTBL-M	NiTin Wedge Small Refill: 50 count	45007	Q01010401
NTGR	NiTin Wedge Large Refill: 100 count	45007	Q01010401
NTGR-M	NiTin Wedge Large Refill: 50 count	45007	Q01010401
NTK4	NiTin Wedge Kit: 400 assorted wedges	45007	Q01010401
NTK4-M	NiTin Wedge Kit: 200 assorted wedges	45007	Q01010401
NTOR	NiTin Wedge Medium Refill: 100 count	45007	Q01010401
NTOR-M	NiTin Wedge Medium Refill: 50 count	45007	Q01010401
NTYL	NiTin Wedge X-Small Refill: 100 count	45007	Q01010401
NTYL-M	NiTin Wedge X-Small Refill: 50 count	45007	Q01010401
QK4	Quad Wedge Kit: 400 count	45007	Q01010401
QK4-M	Quad Wedge Kit: 200 count	45007	Q01010401
QPL	Quad Wedge Purple Refill: 100 count	45007	Q01010401
QBL	Quad Wedge Blue Refill: 100 count	45007	Q01010401
QOR	Quad Wedge Orange Refill: 100 count	45007	Q01010401
QGR	Quad Wedge Green Refill: 100 count	45007	Q01010401
QPL-M	Quad Wedge Purple Refill: 50 count	45007	Q01010401
QBL-M	Quad Wedge Blue Refill: 50 count	45007	Q01010401
QOR-M	Quad Wedge Orange Refill: 50 count	45007	Q01010401
QGR-M	Quad Wedge Green Refill: 50 count	45007	Q01010401

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SKU	Description	GMDN	EMDN
GWAYL	A+Wedge X-Small Yellow Refill: 100 Count	45007	Q01010401
GWABL	A+Wedge Small Blue Refill: 100 Count	45007	Q01010401
GWAOR	A+Wedge Medium Orange Refill: 100 Count	45007	Q01010401
GWAGR	A+Wedge Large Green Refill: 100 Count	45007	Q01010401
GWAK4	A+Wedge Complete Assorted Kit: 50 Yellow, 50 Blue, 50 Orange and 50 Green	45007	Q01010401
GSWYL	G-Wedge Yellow Single Refill: 100 Count	45007	Q01010401
GSWBL	G-Wedge Blue Single Refill: 100 Count	45007	Q01010401
GSWOR	G-Wedge Orange Single Refill: 100 Count	45007	Q01010401
GSWGR	G-Wedge Green Single Refill: 100 Count	45007	Q01010401
GWYL	G-Wedge Yellow Refill: 300 Count	45007	Q01010401
GWYL-E	G-Wedge Yellow Refill: 50 count	45007	Q01010401
GWBL	G-Wedge Blue Refill: 300 Count	45007	Q01010401
GWBL-E	G-Wedge Blue Refill- Package of 50	45007	Q01010401
GWOR	G-Wedge Orange Refill: 300 Count	45007	Q01010401
GWOR-E	G-Wedge Orange Refill: 50 count	45007	Q01010401
GWGR	G-Wedge Green Refill: 300 Count	45007	Q01010401
GWGR-E	G-Wedge Green Refill: 50 count	45007	Q01010401
GWK4	G-Wedge Kit: 100 Yellow, 100 Blue, 100 Orange and 100 Green	45007	Q01010401
SWCYL	Wedge Wands Cure-Through Yellow Refill: 100 Count	45007	Q01010401
SWCBL	Wedge Wands Cure-Through Blue Refill: 100 Count	45007	Q01010401
SWCOR	Wedge Wands Cure-Through Orange Refill: 100 Count	45007	Q01010401
SWCGR	Wedge Wands Cure-Through Green Refill: 100 Count	45007	Q01010401
SWYL	Wedge Wands Yellow Refill: 100 Count	45007	Q01010401
SWBL	Wedge Wands Blue Refill: 100 Count	45007	Q01010401
SWOR	Wedge Wands Orange Refill: 100 Count	45007	Q01010401
SWGR	Wedge Wands Green Refill: 100 Count	45007	Q01010401
WK4	Wedge Wands Kit: 100 Yellow, 100 Blue, 100 Orange and 100 Green	45007	Q01010401

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