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EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices

Document Number:	DOC-EU-INSTRUMENTS
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:	Instruments Family
Technical Document Reference No:	TFMDRINSTRUMENTS
Basic UDI-DI	081003809InstrumentsTFTF
GMDN Code(s) and Description(s):	31814 - Dental dressing forceps, reusable 41861 - Dental restoration carver, resin
EMDN Code(s) and Description(s):	L15901101 - POSITIONING INSTRUMENTS FOR DENTAL MATRICES, REUSABLE L159013 - DENTAL SPATULAS, REUSABLE L159012 - ENDODONTIC SPREADERS AND PLUGGERS, REUSABLE
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 ISO 17664-1:2021 ISO 17664-2:2023 Regulation (EU) 2017/745
Intended Purpose:	The Instruments Family is intended for use by dental professionals as part of a matrix restoration system during restorative dental procedures. The instruments assist in the placement, manipulation, adaptation, contouring, shaping, and removal of matrix system components and restorative materials to support the creation of functional and esthetic dental restorations while minimizing damage to adjacent teeth and tissues.

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

SKU	Description	GMDN	EMDN
CF100	PerForm- proximal contact instrument small: 2 Count	41861	L159013
CF100-S	PerForm- proximal contact instrument small: 1 Count	41861	L159013
CF200	PerForm- proximal contact instrument large: 2 Count	41861	L159013
CF200-S	PerForm- proximal contact instrument large: 1 Count	41861	L159013
CFK01	PerForm- Proximal Contact Instrument Kit	41861	L159013
BWI	Band Wedge Instrument	31814	L15901101
BFA-1	Composi-Tight Matrix Forceps	31814	L15901101
FXP01	Composi-Tight 3D Fusion Ring Placement Forceps	31814	L15901101
AUMRDF-100	Composi-Tight, Gold Handle Ring Placement Forceps	31814	L15901101
MRDF-100	Ring Placement Forceps	31814	L15901101
UNVF-100	Composi-Tight Universal Forceps	31814	L15901101
NTG-MRDF-100	NiTin Garrison Ring Placement Forceps	31814	L15901101
NT-MRDF-100	NiTin Ring Placement Forceps	31814	L15901101
NTG-DF6-8	NiTin Garrison Band Forceps	31814	L15901101
NT-DF6-8	NiTin Band Forceps	31814	L15901101
TN001	Medium Blades Composite Instrument	41861	L159013
TN002	Medium Blade with Medium Plugger Composite Instrument	41861	L159013
TN003	Medium Blade with Large Plugger Composite Instruments	41861	L159013
TN004	Extra Thin Blades Composite Instrument	41861	L159013
TN005	Long Extra Thin Blades Composite Instrument	41861	L159013
TN006	Small/Medium Multi-Function Plugger Composite Instrument	41861	L159012
TN008	Universal Composite Instrument	41861	L159013
TN009	Multi-Function 5-in-1 Composite Instrument	41861	L159013

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