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EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices

Document Number:	DOC-EU-POLISHERSABRASIVES
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 Polishers & Abrasives Family
Technical Document Reference No:	TFMDRPOLISHERSABRASIVES
Basic UDI-DI	081003809PolishersTFAC
GMDN Code(s) and Description(s):	31833 - Dental abrasive point, reusable 35702 - Dental abrasive strip, single-use
EMDN Code(s) and Description(s):	Q01010403 – DENTAL ABRASIVE AND POLISHING MATERIALS Q010499 - ORTHODONTIC 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 ISO 14971:2019+A11:2021 ISO 17664-1 ISO 17664-2 ISO/TR 24971:2020 ISO 15223-1:2021 ISO 20417:2021 Regulation (EU) 2017/745
Intended Purpose:	The Polishers & Abrasives Family is intended for use by dental professionals during restorative and orthodontic procedures for the finishing, contouring, adjustment, and polishing of dental restorations and tooth surfaces. The devices are used to improve restoration anatomy, surface smoothness, and esthetics while supporting the function and longevity of dental restorations.

Declaration

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

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SKU	Description	GMDN	EMDN
FPSCDS	FitStrips double-sided coarse grit Green	35702	Q01010403
FPSCDS-1	FitStrips double-sided coarse grit Green	35702	Q01010403
FPSCDS-4	FitStrips double-sided coarse grit Green	35702	Q01010403
FPSCSS	FitStrips single-sided coarse grit Green	35702	Q01010403
FPSCSS-1	FitStrips single-sided coarse grit Green	35702	Q01010403
FPSCSS-4	FitStrips single-sided coarse grit Green	35702	Q01010403
FPSFDS	FitStrips double-sided fine grit Red	35702	Q01010403
FPSFDS-1	FitStrips double-sided fine grit Red	35702	Q01010403
FPSFDS-4	FitStrips double-sided fine grit Red	35702	Q01010403
FPSFSS	FitStrips single-sided fine grit Red	35702	Q01010403
FPSFSS-1	FitStrips single-sided fine grit Red	35702	Q01010403
FPSFSS-4	FitStrips single-sided fine grit Red	35702	Q01010403
FPSGAUGE	FitStrip IPR Gauge	35702	Q010499
FPSHANDLE	FitStrips handle- 1 handle	35702	Q010499
FPSHANDLE-2	FitStrips handles- 2 handles	35702	Q010499
FPSK01	FitStrips starter kit	35702	Q01010403
FPSK04	FitStrip Universal Kit	35702	Q01010403
FPSK05	FitStrip IPR Kit	35702	Q01010403
FPSK07	FitStrip Subgingival Finishing Kit	35702	Q01010403
FPSK08	FitStrip Subgingival Finishing and Single-Sided Kit	35702	Q01010403
FPSGXFSS	FitStrip Subgingival single-sided super fine grit	35702	Q01010403
FPSGFSS	FitStrip Subgingival single-sided fine grit	35702	Q01010403
FPSGMSS	FitStrip Subgingival single-sided medium grit	35702	Q01010403
FPSGXFSS-4	FitStrip Subgingival single-sided super fine grit	35702	Q01010403
FPSGFSS-4	FitStrip Subgingival single-sided fine grit	35702	Q01010403
FPSGMSS-4	FitStrip Subgingival single-sided medium grit	35702	Q01010403
FPSGXFSS-1	FitStrip Subgingival single-sided super fine grit	35702	Q01010403
FPSGFSS-1	FitStrip Subgingival single-sided fine grit	35702	Q01010403
FPSGMSS-1	FitStrip Subgingival single-sided medium grit	35702	Q01010403
FPSMDS	FitStrips double-sided medium grit Blue	35702	Q01010403
FPSMDS-1	FitStrips double-sided medium grit Blue	35702	Q01010403
FPSMDS-4	FitStrips double-sided medium grit Blue	35702	Q01010403
FPSMSS	FitStrips single-sided medium grit	35702	Q01010403
FPSMSS-1	FitStrips single-sided medium grit	35702	Q01010403
FPSMSS-4	FitStrips single-sided medium grit	35702	Q01010403
FPSS01	FitStrip trial kit	35702	Q01010403
FPSS02	FitStrip IPR Sample Pack	35702	Q01010403
FPSS03	FitStrip Subgingival Sample Pack	35702	Q01010403
FPSSAW	FitStrips serrated refill	35702	Q01010403
FPSSAW-1	FitStrips serrated-1 strip	35702	Q01010403
FPSSAW-4	FitStrips serrated: 4 count	35702	Q01010403
FPSTMDS	FitStrip .40mm double-sided medium grit	35702	Q01010403
FPSTMDS-1	FitStrip .40mm double-sided medium grit- 1 strip	35702	Q01010403
FPSTMDS-4	FitStrip .40mm double-sided medium grit- 4 count	35702	Q01010403
FPSXFDS	FitStrips double-sided super fine grit	35702	Q01010403
FPSXFDS-1	FitStrips double-sided super fine grit- 1 strip	35702	Q01010403
FPSXFDS-4	FitStrips double-sided super fine grit: 4 count	35702	Q01010403
FPSXFSS	FitStrips single-sided super fine	35702	Q01010403
FPSXFSS-1	FitStrips single-sided super fine-single-1 strip	35702	Q01010403
FPSXFSS-4	FitStrips single-sided super fine: 4 count	35702	Q01010403
FPSXTMDS	FitStrip .50mm double-sided medium grit	35702	Q01010403
FPSXTMDS-1	FitStrip .50mm double-sided medium grit- 1 strip	35702	Q01010403

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SKU	Description	GMDN	EMDN
FPSXTMDS-4	FitStrip .50mm double-sided medium grit- 4 count	35702	Q01010403
FPZC010-X	eZr Blue coarse grit flat end taper grinder, 5/pack	31833	Q01010403
FPZC030-X	eZr Blue coarse grit disc grinder, 5/pack	31833	Q01010403
FPZF010-X	eZr Orange fine grit small point polisher, 5/pack	31833	Q01010403
FPZF020-X	eZr Orange fine grit large point polisher, 5/pack	31833	Q01010403
FPZF030-X	eZr Orange fine grit disc polisher, 5/pack	31833	Q01010403
FPZF040-X	eZr Orange fine grit cup polisher, 5/pack	31833	Q01010403
FPZK01-X	eZr Complete System Kit	31833	Q01010403
FPZM010-X	eZr Green medium grit small point polisher, 5/pack	31833	Q01010403
FPZM020-X	eZr Green medium grit large point polisher, 5/pack	31833	Q01010403
FPZM030-X	eZr Green medium grit disc polisher, 5/pack	31833	Q01010403
FPZM040-X	eZr Green medium grit cup polisher, 5/pack	31833	Q01010403

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