

DECLARATION OF CONFORMITY

Manufacturer:

Garrison Dental Solutions
150 DeWitt Lane
Spring Lake
MI 49456
USA

SRN:

US-MF-000004112

EU Authorised 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 apparatus

Conforming Apparatus:

Slick Bands

GMDN:

38786

Basic UDI-DI:

081003809BandsTFXZ

Device Name and UDI-DI Numbers:

See Page 2 and 3 below

Risk Class:

Class I - MDR Annex VIII Rule 1

Technical Document Reference No:

TFMDR BANDS

Common Specifications

EN ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices

Medical Devices Regulations – Annex I, General Requirements

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 5 April 2017 on medical devices

Signed:

Date: 9 December 2021



Issued: Dublin, Ireland

Michael Morris
Garrison Dental Solutions

Device Name	Device Model	Device UDI-DI GTIN
Slick Bands™ Trial Pack: 35 Count	SBSP1	00810038096063
Slick Bands™ Pedodontic Matrix with Extension: 60 Count	SM050	10810038093090
Slick Bands™ Bicuspid Matrix Grey: 100 Count	SM100	30810038093117
Slick Bands™ Bicuspid Matrix Grey: 25 Count	SM100-E	10810038093113
Slick Bands™ Bicuspid Matrix Grey: 50 Count	SM100-M	20810038093110
Slick Bands™ Bicuspid Matrix with Extension Red: 60 Count	SM150	30810038093100
Slick Bands™ Bicuspid Matrix with Extension Red: 15 Count	SM150-E	10810038093106
Slick Bands™ Bicuspid Matrix with Extension Red: 30 Count	SM150-M	20810038093103
Slick Bands™ 5.5mm Molar Matrix Purple: 100 Count	SM175	30810038093131
Slick Bands™ 5.5mm Molar Matrix Purple: 25 Count	SM175-E	10810038093137
Slick Bands™ 5.5mm Molar Matrix Purple: 50 Count	SM175-M	20810038093134
Slick Bands™ Molar Matrix Green: 100 Count	SM200	30810038093124
Slick Bands™ Molar Matrix Green: 25 Count	SM200-E	10810038093120
Slick Bands™ Molar Matrix Green: 50 Count	SM200-M	20810038093127
Slick Bands™ Molar Matrix with Extension Blue: 60 Count	SM300	30810038093087
Slick Bands™ Molar Matrix with Extension Blue: 15 Count	SM300-E	10810038093083
Slick Bands™ Molar Matrix with Extension Blue: 30 Count	SM300-M	20810038093080
Slick Bands™ Multi-Band Refill Kit: 420 Count	SMBRP1	00810038096070
Slick Bands™ Assorted Mini Kit: Contains 200 Matrices	SMBRP1-M	00810038096087
#13 Pedo Non-Stick Matrix Band Dead Soft: 100 per Pack	SMT050D10	20810038093424
#13 Pedo Non-Stick Matrix Band Dead Soft: 50 per Pack	SMT050D10-M	10810038093427
#13 Pedo Non-Stick Matrix Band Regular: 100 per Pack	SMT050H10	20810038093431
#13 Pedo Non-Stick Matrix Band Regular: 50 per Pack	SMT050H10-M	10810038093434
Slick Bands™ #1 Universal Dead Soft Tofflemire Matrix Green: 100 per Pack	SMT200D10	20810038093448
Slick Bands™ #1 Universal Dead Soft Tofflemire Matrix Green: 50 per Pack	SMT200D10-M	10810038093441
Slick Bands™ #1 Universal Regular Tofflemire Matrix Gray: 100 per Pack	SMT200H10	20810038093455
Slick Bands™ #1 Universal Regular Tofflemire Matrix Gray: 50 per Pack	SMT200H10-M	10810038093458
#2 Subgingival Non-Stick Matrix Band Dead Soft: 100 per Pack	SMT300D10	20810038093462
#2 Subgingival Non-Stick Matrix Band Dead Soft: 50 per Pack	SMT300D10-M	10810038093465
#2 Subgingival Non-Stick Matrix Bands Regular: 100/Pack	SMT300H10	20810038093479
#2 Subgingival Non-Stick Matrix Bands Regular: 50/Pack	SMT300H10-M	10810038093472
Right-Curve Tofflemire Matrix Bands Dead Soft: 100/Package	SMT400D10	20810038093486
Right-Curve Tofflemire Matrix Bands Dead Soft: 50/Package	SMT400D10-M	10810038093489
Right-Curve Tofflemire Matrix Bands Regular: 100/Package	SMT400H10	20810038093493
Right-Curve Tofflemire Matrix Bands Regular: 50/Package	SMT400H10-M	10810038093496
Slick Bands™ Tofflemire Margin Elevation Matrix: 100/Pack	SMT500H10	30810038093506
Slick Bands™ Margin Elevation Matrix: 50/Pack	SMT500H10-M	20810038093509
Slick Bands™ Margin Elevation Matrix Sample Pack: 20/Pack	SMT500S01	10810038093502
Slick Bands™ Tofflemire Kit with G-Wedge™ and PerForm™ Instruments	SMTK06	00810038096094
Slick Bands™ Tofflemire Trial Pack	SMTR01	00810038096100
Slick Bands™ XR Bicuspid Matrix Gray: 100 Count	SXR100	20810038092694
Slick Bands™ XR Bicuspid Matrix Gray: 50 Count	SXR100-M	10810038092697
Slick Bands™ XR Bicuspid Matrix with Extension Red: 60 Count	SXR150	20810038092700
Slick Bands™ XR Bicuspid Matrix with Extension Red: 30 Count	SXR150-M	10810038092703
Slick Bands™ XR 5.5mm Molar Matrix Purple: 100 Count	SXR175	20810038092717

Slick Bands™ XR 5.5mm Molar Matrix Purple: 50 Count	SXR175-M	10810038092710
Slick Bands™ XR Molar Matrix Green: 100 Count	SXR200	20810038092724
Slick Bands™ XR Molar Matrix Green: 50 Count	SXR200-M	10810038092727
Slick Bands™ XR Molar Matrix with Extension Blue: 60 Count	SXR300	20810038092731
Slick Bands™ XR Molar Matrix with Extension Blue: 30 Count	SXR300-M	10810038092734
Slick Bands™ XR Trial Pack: 25 Count	SXRB01	00810038096131
Slick Bands™ XR Band Refill Kit: 420 Count	SXRB02	00810038096148