

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:

Placement Forceps

GMDN:

31814

Basic UDI-DI:

081003809InstrumentsTFTF

Device Name, Model and UDI-DI/GTIN Numbers:

Composi-Tight® 3D Fusion™ Ring Placement Forceps
FXP01 - 00810038094557
Composi-Tight® Universal Forceps
UNVF-100 - 00810038094809
Composi-Tight® Silver Handle Ring Placement Forceps
MRDF-100 - 00810038094854
Composi-Tight® Matrix Forceps
BFA-1 - 00810038093772
Composi-Tight, Gold Handle Ring Placement Forceps
AUMRDF-100 - 00810038093758
NiTin Garrison® Band Forceps
NTG-DF6-8 - 00810038094670
NiTin Garrison® Ring Placement Forceps
NTG-MRDF-100 - 00810038094687

Risk Class:

Class I - MDR Annex VIII Rule 1

Technical Document Reference No:

TFMDRINSTRUMENTS

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