

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:

Compositite Instruments

GMDN

41861

Basic UDI-DI:

081003809InstrumentsTFTF

Device Name and UDI-DI Numbers:

See Page 2 below

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

Device Name	Device Model	Device UDI-DI GTIN
Medium Blade Composite Instrument	TN001	00810038094724
Medium Blade with Medium Plugger Composite Instrument	TN002	00810038094731
Medium Blade with Large Plugger Composite Instrument	TN003	00810038094748
Extra Thin Blade Composite Instrument	TN004	00810038094755
Long Extra Thin Blade Composite Instrument	TN005	00810038094762
Small/Medium Multi-Function Plugger Composite Instrument	TN006	00810038094779
Universal Composite Instrument	TN008	00810038094786
Multi-Function 5-in-1 Composite Instrument	TN009	00810038094793