

Doc. No. - DOC005	Revision: A	Effective Date: March 7, 2025	DCR: 25-043
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Single Registration Number	
US-MF-000013090	
Conformity Assessment	
Device Classification	Class IIa
Device Classification Rule	Annex VIII, Rule 5
Quality Management Certificate #:	MD 635659
Notified Body	
BSI (2797) Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands CE Certificate# MDR 768187 R000	
European Authorized Representative	
SRN:	NL-AR-000022839
G&H Europe BV Edisonstraat 3 3861 Nijkerk Netherlands	

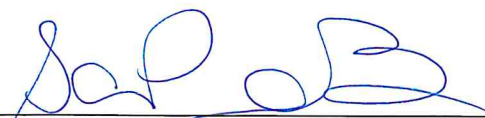
- I. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.
- II. Manufacturer declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the Medical Devices Regulations (EU) 2017/745 Annex IX Chapter I and III and carried out according to the Quality Management System ISO 13485:2016.
- III. Please reference the General Safety and Performance Requirements for a list of all applicable standards and common specifications.

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with...)
12-028	<i>Hooks provide a method to transfer force from a wire, spring, elastic, or other force containing device to a tooth in order to facilitate orthodontic treatment.</i>	Hooks Ball Clasps	Basic UDI-DI: 0195291AuxiliariesA9 122*
14-457	<i>Ligature wires assist in creating the forces necessary to move teeth during orthodontic treatment.</i>	Ligature Wires Bulk Ligature Wire Kobayashi Ties Performed Ligature	Basic UDI-DI: 0195291LigatureWiresQL 122* 122* 121*
16-190	<i>Orthodontic elastics are used in orthodontic treatment to exert a force. Elastomeric chain is placed around the tie wings on the bracket to retain the archwire in the bracket slot and extended to other teeth to provide force.</i>	Elastic Chain, Orthodontic Chain Elastic	Basic UDI-DI: 0195291ElasticChain62 340*
	<i>Orthodontic elastics are used in orthodontic treatment to exert a force.</i>	Elastic Bands, Orthodontic Intraoral Elastics	Basic UDI-DI: 0195291ElasticBands62 340*

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16-190	<i>Ligature ties are intended to be placed around the tie wings on the bracket to retain the archwire in the bracket slot.</i>	Elastic Ligature Tie, Orthodontic	Basic UDI-DI: 0195291LigatureTiesQ3
		S-Ties	ST*
16-199	<i>Tubes are intended to be affixed to the teeth, molar bands or slide onto the archwire to provide an anchor for a wire or other appliance.</i>	Orthodontic Tubes	Basic UDI-DI: 0195291MetalTubesF4
		Tubes – Misc	HS1*
16-204	<i>Wires provide force to move the teeth into the desired Class I bite and to maintain the formation of the teeth until the roots of the teeth remain in the preferred position.</i>	Orthodontic Wires	
		Type 2 Wire	Basic UDI-DI: 0195291Type2OrthowiresUK
		Nickel Titanium Archwires	111*
		Heat-Activated/ Thermal Nickel Titanium Archwires	112*
		Spools & Straight Lengths	111* 112*
		Type 1 Wire	Basic UDI-DI: 0195291Type1OrthowiresTL
		Stainless Steel Archwires	122* 123*
		Stainless Steel Spooled & Straight Lengths	122* 127*
		TitanMoly Archwires	130*
		Straight Lengths	130*
16-360	<i>Orthodontic brackets provide a base to create force to move a tooth in order to facilitate orthodontic treatment.</i>	Orthodontic Brackets	
		Stainless Steel Brackets	Basic UDI-DI: 0195291MetalBracketsZA
		Misc Brackets	150*
33-907	<i>Springs are intended to open or close a space between teeth or to prevent molar tipping.</i>	Orthodontic Springs	
		Nickel Titanium Springs	Basic UDI-DI: 0195291NiTiSpringsJN
		Nickel Titanium Springs	111*

Signed in Franklin 2025-March-07 on behalf of Flexmedics



SaPrina Bemis

Regulatory Affairs Manager

Person Responsible for Regulatory Compliance