



Doc. No. - DOC005

Revision: A

Effective Date: March 7, 2025

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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**

<b>SRN:</b>	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>	<b>Hooks</b>	<b>Basic UDI-DI: 0195291AuxiliariesA9</b>
		Ball Clasps	122*
14-457	<i>Ligature wires assist in creating the forces necessary to move teeth during orthodontic treatment.</i>	<b>Ligature Wires</b>	<b>Basic UDI-DI: 0195291LigatureWiresQL</b>
		Bulk Ligature Wire	122*
		Kobayashi Ties	122*
		Performed Ligature	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>	<b>Elastic Chain, Orthodontic</b>	<b>Basic UDI-DI:0195291ElasticChain62</b>
		Chain Elastic	340*
	<i>Orthodontic elastics are used in orthodontic treatment to exert a force.</i>	<b>Elastic Bands, Orthodontic</b>	<b>Basic UDI-DI: 0195291ElasticBands62</b>
		Intraoral Elastics	340*



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DCR: 25-043

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with...)
16-190	Ligature ties are intended to be placed around the tie wings on the bracket to retain the archwire in the bracket slot.	<b>Elastic Ligature Tie, Orthodontic</b>	<b>Basic UDI-DI: 0195291LigatureTiesQ3</b>
		S-Ties	ST*
16-199	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.	<b>Orthodontic Tubes</b>	<b>Basic UDI-DI: 0195291MetalTubesF4</b>
		Tubes – Misc	HS1*
16-204	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.	<b>Orthodontic Wires</b>	
		<b>Type 2 Wire</b>	<b>Basic UDI-DI: 0195291Type2OrthowiresUK</b>
		Nickel Titanium Archwires	111*
		Heat-Activated/ Thermal Nickel Titanium Archwires	112*
		Spools & Straight Lengths	111* 112*
		<b>Type 1 Wire</b>	<b>Basic UDI-DI: 0195291Type1OrthowiresTL</b>
		Stainless Steel Archwires	122* 123*
		Stainless Steel Spooled & Straight Lengths	122* 127*
		TitanMoly Archwires	130*
		Straight Lengths	130*
16-360	Orthodontic brackets provide a base to create force to move a tooth in order to facilitate orthodontic treatment.	<b>Orthodontic Brackets</b>	
		<b>Stainless Steel Brackets</b>	<b>Basic UDI-DI: 0195291MetalBracketsZA</b>
		Misc Brackets	150*
33-907	Springs are intended to open or close a space between teeth or to prevent molar tipping.	<b>Orthodontic Springs</b>	
		<b>Nickel Titanium Springs</b>	<b>Basic UDI-DI: 0195291NiTiSpringsJN</b>
		Nickel Titanium Springs	111*



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

SaPrina Bemis  
Regulatory Affairs Manager  
Person Responsible for Regulatory Compliance