

Doc. No. - DOC005	Revision: 0	Effective Date: February 6, 2024	DCR: 24-016
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<b>Single Registration Number</b>	
US-MF-000013090	
<b>Conformity Assessment</b>	
Device Classification	Class IIa
Conformity Assessment Route	Annex VIII, Rule 5
Quality Management Certificate #:	MD 635659
<b>Notified Body</b>	
BSI (2797) Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands CE Certificate# MDR 768187 R000	
<b>European Authorized Representative</b>	
<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>
		<i>Ball Clasps</i>	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>
		<i>Bulk Ligature Wire</i>	122*
		<i>Kobayashi Ties</i>	122*
		<i>Performed Ligature</i>	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>
		<i>Chain Elastic</i>	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>
		<i>Intraoral Elastics</i>	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>	<b>Elastic Ligature Tie, Orthodontic</b>	<b>Basic UDI-DI: 0195291LigatureTiesQ3</b>
		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>	<b>Orthodontic Tubes</b>	<b>Basic UDI-DI: 0195291MetalTubesF4</b>
		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>	<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	<i>Orthodontic brackets provide a base to create force to move a tooth in order to facilitate orthodontic treatment.</i>	<b>Orthodontic Brackets</b>	
		<b>Stainless Steel Brackets</b>	<b>Basic UDI-DI: 0195291MetalBracketsZA</b>
		Misc Brackets	150*
33-907	<i>Springs are intended to open or close a space between teeth or to prevent molar tipping.</i>	<b>Orthodontic Springs</b>	
		<b>Nickel Titanium Springs</b>	<b>Basic UDI-DI: 0195291NiTiSpringsJN</b>
		Nickel Titanium Springs	111*

Signed in Franklin 2024-February-06 on behalf of Flexmedics



John Browder  
 Director, RA/QA  
 Person Responsible for Regulatory Compliance