

Doc. No. - DOC003

Revision: 0

Effective Date: February 6, 2024

DCR: 24-016

Flexmedics
40 Linville Way
Franklin, IN 46131, United States

T: +1 (317) 346-6655
F: +1 (317) 346-6663
E-mail: orders@ghortho.com

Single Registration Number

US-MF-000013090

Conformity Assessment

Device Classification	Class I
Conformity Assessment Route	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# Not Applicable for Class I Devices

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 II 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...)
16-350	A performed impression tray is intended to hold impression material, to reproduce the structure of a patient's teeth and gums.	Disposable Impression Tray	Basic UDI-DI: 0195291DisplmpTraysAT
		Disposable Impression Tray	DIT*
16-191	Extraoral Headgear is device intended to exert pressure on the teeth from outside the mouth. It is designed for intrusion and extrusion of molars, expansion, and distalization.	Extra-oral Headgear	Basic UDI-DI: 0195291Headgear79
		Facemasks	PFM* RPFM*
		Highpull Headcaps	HPL* HPS SOF*
		Neckpads	CP*
		Safety Modules	SRD* SRB*
16-189		Dental Wax	Basic UDI-DI: 0195291DentalWax6U

Doc. No. - DOC003

Revision: 0

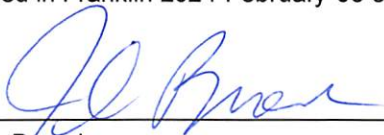
Effective Date: February 6, 2024

DCR: 24-016

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with...)
	<i>Orthodontic Wax is intended to protect the inner lips from the brackets or wires or the take a bite impression.</i>	<i>Bite Wax</i>	BWX*
		<i>Patient Wax/ Flavor Wax</i>	PWX*
		<i>Utility Wax</i>	UWX*

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with...)
16-350	<i>A performed impression tray is intended to hold impression material, to reproduce the structure of a patient's teeth and gums.</i>	Disposable Impression Tray	Basic UDI-DI: 0195291DispImpTraysAT
		<i>Disposable Impression Tray</i>	DIT*
16-191	<i>Extraoral Headgear is device intended to exert pressure on the teeth from outside the mouth. It is designed for intrusion and extrusion of molars, expansion, and distalization.</i>	Extra-oral Headgear	Basic UDI-DI: 0195291Headgear79
		<i>Facemasks</i>	PFM* RPFM*
		<i>Highpull Headcaps</i>	HPL* HPS SOF*
		<i>Neckpads</i>	CP*
		<i>Safety Modules</i>	SRD* SRB*
16-189	<i>Orthodontic Wax is intended to protect the inner lips from the brackets or wires or the take a bite impression.</i>	Dental Wax	Basic UDI-DI: 0195291DentalWax6U
		<i>Bite Wax</i>	BWX*
		<i>Patient Wax/ Flavor Wax</i>	PWX*
		<i>Utility Wax</i>	UWX*

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



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