G&H Wire Company, Inc.

G&H Wire Company, Inc.
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Single Registration Number	
US-MF-000012129	
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	
G&H Europe BV Edisonstraat 3 3681 Nijikerk Netherlands	

I. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

II. The quality management system of the manufacturer has been approved by the notified body BSI according to European Medical Device Regulation 2017/745 Annex IX and EN ISO 13485:2016 compliant system.

III. Please reference the Summary Technical Document 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:0190886DispImpTrayGE***
		Disposable Impression Tray	DIT* CLIPCP* OM*
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: 0190886Headgear9Y***
		Facemasks	PFM* RPFM* CLIM* AD* OM*
		Highpull Headcaps	HPL* HPS SOF*
		Neckpads	CP* CLI* OM*
		Safety Modules	SRD* SRB* CLIM*
16-189	*Orthodontic Wax is intended to protect the inner lips from the brackets or wires*	***Dental Wax***	***Basic UDI-DI:0190886DentalWaxAX***
		Bite Wax	BWX*
		Patient Wax/ Flavor Wax	PWX*
		Utility Wax	UWX*

UMD NS Code	Intended Purpose	Product Family / Description	Part number Prefix (Part Number begins with…)
	or the take a bite impression.		

We, G&H Wire Company, Inc. of Franklin, Indiana, USA, hereby declare with sole responsibility that the medical devices listed above conform to the applicable standards identified above and the provision of European Medical Device Regulation (MDR) 2017/745 Annex IX.

Signed this 13 day of July, *2022* by

John Browder
Director, RA/QA