

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

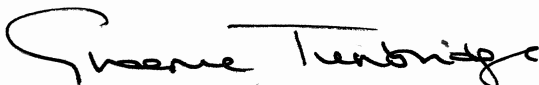
No. UKCA 778128
Issued To: G&H Wire Company, Inc
dba Highland Metals Inc., Flexmedics,
OrthoClub, G&H Orthodontics,
Orthodontic Design & Production
40 Linville Way
Franklin
Indiana
46131
USA

In respect of:

Manufacture of Elastomers, Non-latex Intraoral Elastics, Hooks, Elastic Bands, Orthodontic Wires, Orthodontic Springs, Orthodontic Expanders, Ligature Wires, Expansion Screws, Orthodontic Bands, Orthodontic Tubes and Orthodontic Brackets.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-10-03**

Date: **2022-10-03**

Expiry Date: **2027-10-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 778128

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 USA**

Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 0402	Orthodontic Brackets, Bands, Hooks & Anchoring Auxiliaries	---
MD 0402	Orthodontic Ligatures and Wires	---
MD 0402	Orthodontic Elastomerics and Springs	---

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Certificate History

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Date	Reference Number	Action
Current	3753524	First Issue and renewal – traceable to CE 635654

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