

# 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]

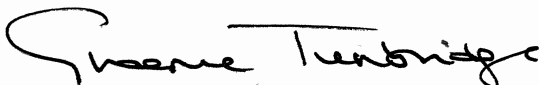
**No.** UKCA 778176  
**Issued To:** Flexmedics  
40 Linville Way  
Franklin  
Indiana  
46131  
USA

In respect of:

**Manufacture and final inspection of non-sterile Elastomers, Non-latex Intraoral Elastics, Hooks, Elastic Bands, Orthodontic Wires, Orthodontic Springs, Ligature Wires, Orthodontic Bands, Orthodontic Tubes, Orthodontic Brackets and Anchoring Auxiliaries**

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: **2022-10-10**

Date: **2022-10-10**

Expiry Date: **2027-10-09**

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## Supplementary Information to UKCA 778176

Issued To:

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40 Linville Way  
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46131  
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Device code	Device name	Intended purpose per IFU
<b>Class IIa</b>		
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 635656

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