



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 768187 R000

Manufacturer: Flexmedics

Address:

40 Linville Way Franklin Indiana 46131 USA

Single Registration Number: US-MF-000013090

EU Authorised Representative: G&H Europe BV

Address:Edisonstraat 3
Nijkerk 3861
The Netherlands

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: 2022-09-29 Starting Validity Date: 2022-12-16

Current Issue Date: **2022-12-16** Expiry Date: **2027-09-28**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	1
Orthodontic Elastomerics and Springs	Class IIa Non-Implantable	
Orthodontic Brackets, Tubes, Bands, Hooks, and Anchoring	Class IIa Non-Implantable	CE TO
Auxiliaries		
Orthodontic Wires	Class IIa Non-Implantable	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate. Verification@bsigroup.com)

Date	Reference Number	Action
2022-09-29	3653030	Issued
Current 3811551	Amended – Change of EU Authorised Representative to	
	G&H Europe BV, Edisonstraat 3, Nijkerk, 3861, Netherlands	
	Amended – Removal of subcontractor	
	Supplemented – Addition of device subcategory	
	Orthodontic Brackets, Tubes, Bands, Hooks, and Anchoring	
	Auxiliaries	
	Supplemented – Addition of device subcategory	
	Orthodontic Wires	

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