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**

Current Issue Date: **2022-12-16**

Starting Validity Date: **2022-12-16**

Expiry Date: **2027-09-28**

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

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