

30 March 2022

FlexMedics  
40 Linville Way  
Franklin  
Indiana  
46131  
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 635656	93/42/EEC Annex V	3657221	Change of manufacturer address to 40 Linville Way, Franklin, Indiana 46131.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge  
Senior Vice President, Medical Devices

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 635656  
Issued To: **FlexMedics**  
**2165 Earlywood Drive**  
**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 Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2015-10-09**Date: **2019-02-08**Expiry Date: **2022-10-03**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 635656**  
Date: **2019-02-08**  
Issued To: **FlexMedics**  
**2165 Earlywood Drive**  
**Franklin**  
**Indiana**  
**46131**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Accurate Wire, Inc 8 Baldwin Dr Branford Connecticut 06405 USA	<b>Crucial Supplier</b>
Auradonics 439 Saint Mihiel Drive Riverside New Jersey 08075 USA	<b>Manufacture</b>
CDB-Corporation Inc. 9201 Industrial Blvd. Leland North Carolina 28451 USA	<b>Manufacture</b>

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Directive 93/42/EEC on Medical Devices, Annex V

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**Franklin**  
**Indiana**  
**46131**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Fort Wayne Metals Research Products Corporation 9609 Ardmore Avenue Fort Wayne Indiana 46809 USA	<b>Crucial Supplier</b>
Kent Elastomers 1500 St Clair Ave Kent Ohio 44240 USA	<b>Crucial Supplier</b>
mdi Europa GmbH Langenhagner Str. 71 30855 Hannover - Langenhagen Germany	<b>EU Representative</b>

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Directive 93/42/EEC on Medical Devices, Annex V

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**Franklin**  
**Indiana**  
**46131**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Ortotec S.A de C.V Prolongación Avenida Benito Juárez El Refugio, Tecate Baja California 21440 Mexico	<b>Crucial Supplier</b>
PPG Industries 1 PPG Place Pittsburgh Pennsylvania 15222 USA	<b>Crucial Supplier</b>
Wire and Cable Specialities, Inc 440 Highlands Blvd Coatesville Pennsylvania 19320 USA	<b>Crucial Supplier</b>

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 635656**  
 Date: **2019-02-08**  
 Issued To: **FlexMedics**  
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**Franklin**  
**Indiana**  
**46131**  
**USA**

Date	Reference Number	Action
09 October 2015	8333753	Transfer of US00/52080 from SGS (0120) with scope: Orthodontic wires, springs, brackets, hooks, bands, tubes, ligature wires, elastic bands, ligature ties, non-latex intraoral elastics, temporary orthodontic implant screws, dental retractors, extraoral headgear, impression trays and positioning aids, glass fiber splints, palatal bars, dental impression materials, dental polishing strips, dental wax, facebows, orthodontic hand instruments, orthodontic retainers, teeth protectors.
29 September 2016	8594784	Change in Route to Conformity from Annex II.3 to Annex V. Removal of Orthodontic Design and Production as subcontractor.
03 October 2017	8745719	Certificate renewal. Addition of suppliers; Accurate Wire (8 Baldwin Dr, Branford, CT 06405, USA), Auradonics (439 Saint Mihiel Drive, Riverside, New Jersey 08075, USA), Fort Wayne Metals (9609 Ardmore Avenue Fort Wayne, IN 46809), Kent Elastomers (1500 St Clair Ave, Kent, Ohio 44240, USA), Wire and cable specialities (440 Highlands Blvd, Coatesville, PA 19320) and PPG Industries (1 PPG Place, Pittsburg, PA 15222, USA). Removal of subcontractors: Prime Dental Manufacturing, Inc and Beijing Smart Technology Co., Ltd.
08 February 2019	8424270	Traceable to NB 0086.

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Date: **2019-02-08**  
Issued To: **FlexMedics  
2165 Earlywood Drive  
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USA**

Date	Reference Number	Action
<b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
30 March 2022	3657221	Change of manufacturer address to 40 Linville Way, Franklin, Indiana 46131.