

30 March 2022

Orthodontic Design and Production
40 Linville Way
Franklin
Indiana
46131
USA

To whom it may concern,

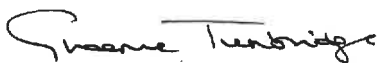
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 649654	93/42/EEC Annex V	3657138	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 649654****Issued To:**

**Orthodontic Design and Production
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: **2016-09-29**

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 649654**
 Date: **2019-02-08**
 Issued To: **Orthodontic Design and Production**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

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

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EC Certificate - Production Quality Assurance

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

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 Date: **2019-02-08**
 Issued To: **Orthodontic Design and Production**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

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

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EC Certificate - Production Quality Assurance

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

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Certificate No: **CE 649654**
 Date: **2019-02-08**
 Issued To: **Orthodontic Design and Production**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

Subcontractor:

Service(s) supplied

Ortotec S.A de C.V
 Prolongación Avenida Benito Juárez
 El Refugio, Tecate
 Baja California
 21440
 Mexico

Crucial Supplier

PPG Industries
 1 PPG Place
 Pittsburgh
 Pennsylvania
 15222
 USA

Crucial Supplier

Wire and Cable Specialities, Inc
 440 Highlands Blvd
 Coatesville
 Pennsylvania
 19320
 USA

Crucial Supplier

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 649654**
Date: **2019-02-08**
Issued To: **Orthodontic Design and Production**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

Date	Reference Number	Action
29 September 2016	8483052	First issue.
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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 March 2022	3657138	Change of manufacturer address to 40 Linville Way, Franklin, Indiana 46131.

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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.