

30 March 2022

Ortho Club
40 Linville Way
Franklin
Indiana
46131
USA

To whom it may concern,

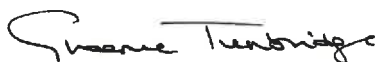
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 635655	93/42/EEC Annex V	3657139	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 635655****Issued To:**

**Ortho Club
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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Page 1 of 1

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 635655**
 Date: **2019-02-08**
 Issued To: **Ortho Club**
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

List of Significant Subcontractors

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

Certificate No: **CE 635655**
Date: **2019-02-08**
Issued To: **Ortho Club**
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
Langenhagener 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

List of Significant Subcontractors

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

Certificate No: **CE 635655**
 Date: **2019-02-08**
 Issued To: **Ortho Club**
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 635655**
 Date: **2019-02-08**
 Issued To: **Ortho Club**
2165 Earlywood Drive
Franklin
Indiana
46131
USA

Date	Reference Number	Action
09 October 2015	8333753	Transfer of US09/74315 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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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 Certificate History

Certificate No: **CE 635655**
Date: **2019-02-08**
Issued To: **Ortho Club**
2165 Earlywood Drive
Franklin
Indiana
46131
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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 March 2022	3657139	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.