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By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 668842**

Issued To: **Ortho Arch Company, Inc.**
1107 Tower Road
Schaumburg
Illinois
60173
USA

In respect of:

Manufacture of non-sterile orthodontic wires, bands, brackets, elastic ligatures and chains.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-06-15** Date: **2020-06-15** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 668842

Issued To:

Ortho Arch Company, Inc.
1107 Tower Road
Schaumburg
Illinois
60173
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD0402	Bands	Realignment of teeth
	Brackets and tubes	
	Wires and springs	
	Elastic ligatures and chains	

First Issued: **2020-06-15** Date: **2020-06-15** Expiry Date: **2024-05-26**

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Ortho Arch Company Inc.
1107 Tower Road
Schaumburg
Illinois
60173
USA

24th May 2024

Notified Body Confirmation Letter
Reference: EU2023-607/873912

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Ortho Arch Company Inc.
1107 Tower Road
60173 City
USA

SRN Number: US-MF-000008544

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Orthodontic Molar Bands **++D909TCF001V9**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Stainless-Steel Brackets **++D909TCF002VB**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Buccal Tubes **++D909TCF002VB**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Lingual Attachments **++D909TCF002VB**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Wires **++D909TCF004VF**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Springs **++D909TCF004VF**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Ligatures and Chains **++D909TCF005VH**	Class IIa	N/A	CE 668842; NB# 2797
Orthodontic Ceramic Brackets **++D909TCF003VD**	Class IIa	N/A	CE 668842; NB# 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	Choose an item.	**N/A**	**N/A**

Confirmation Letter Revision History

Date	Action
2024/05/24	Initial issue

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

No. **CE 668842**

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In respect of:

Manufacture of non-sterile orthodontic wires, bands, brackets, elastic ligatures and chains.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-06-15** Date: **2020-06-15** Expiry Date: **2024-05-26**

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Supplementary Information to CE 668842

Issued To:

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1107 Tower Road
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD0402	Bands	Realignment of teeth
	Brackets and tubes	
	Wires and springs	
	Elastic ligatures and chains	

First Issued: **2020-06-15** Date: **2020-06-15** Expiry Date: **2024-05-26**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ortho Arch Company, Inc.
1107 Tower Road
Schaumburg
Illinois
60173
USA

Facility ID Number: F006184

Holds Certificate No: **MDSAP 772026**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Manufacture and distribution of non-sterile orthodontic devices (archwire, bracket, spring, wire, tube, separator, inter-bracket elastic chain, inter-arch elastic band, rod-based aligner, power arm, progressive aligner, lock, stainless steel band, preformed metal clasp, phototherapy unit, bracket ligature, instruments, and aligner auxiliary attachment), and dental (wedge, polymer-based modeling material.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-04-20 Effective Date: 2026-01-05 Expiry Date: 2029-01-04

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ortho Arch Company, Inc.
1107 Tower Road
Schaumburg
Illinois
60173
USA

Holds Certificate Number: MD 668843

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture and distribution of non-sterile orthodontic devices (archwire, bracket, spring, wire, tube, separator, inter-bracket elastic chain, inter-arch elastic band, rod-based aligner, power arm, progressive aligner, lock, stainless steel band, preformed metal clasp, phototherapy unit, bracket ligature, instruments, and aligner auxiliary attachment), and dental (wedge, polymer-based modeling material).

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-01-05
Effective Date: 2026-01-05
Latest Revision Date: 2025-11-25
Expiry Date: 2029-01-04

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