Audit Report for:

Medical Device Certification
Audit Report

This report is confidential and distribution is limited to the audit team, client representative and the SGS office unless requested by a Regulatory Body entitled to the information contained within.

The audit documentation to support the certification decision includes both the audit report and the associated audit checklist(s) for the audit scope undertaken.

0. CERTIFICATION SUMMARY

Standard	Annex	Accreditation Body
ISO13485:2016	n/a	UKAS
93/42/EEC	Annex II	CE 0120

1. MANUFACTURER/ ORGANISATION

Organisation:	Ortho Technology, Inc.		
Address:	4614 Pet Lane Suite D-101 Lutz FL 33559		
Representative:	Tom Swan – Associate Manager, Quality Systems		
Telephone:	813-501-1651	**E-mail:**	Tom.Swan@henryschein.com

Structure and Trading names of the Manufacturer (Corporate Identity):
Company is owned by Ortho Organizers (aka O2), a division of Henry Schein, as of 2012. Ortho Technology retains an autonomous QMS.

Scope of the certified quality management system:			
Site details & senior manager	**Main activities/ processes on site**	**Effective No of Personnel**	**No of Shifts**
Shawn Potter – Director of Commercial Operations	Receiving, inspection, warehousing, shipping, marketing, customer service, purchasing, (regulatory affairs) 31,000 square feet of warehouse space and additional 10,000 square feet of office space. (OT performs some distribution of Henry Schein products into the EU. OT manufactures and labels some product for American Ortho. OT performs inventory management and shipping for O2.)	68 (V3 was 75)	1

Exclusions and Non-Applications of Requirements in the QMS

Is ISO 13485 Clause 7.3 excluded?	**No**

Any other non-applicable ISO 13485 clauses?	Non-Applicable ISO 13485 clauses: Sterile, Servicing, Installation, Implants

2. AUDIT

Audit type & No.:	Recertification	**Date(s) of audit:**	11-14th September 2018
Site(s) audited:	As above		
EAC Code(s):	14, 17	**NACE Code(s):**	25.24, 28
Tech. Area Code(s):	14.2, 17.4		
Simple Code(s):	14, 17	**Complex Code(s):**	214
Lead auditor (Team Leader):	Roland Cooke	**Additional team member(s): (roles)**	Edna Falkenberg
Additional Attendees and Roles:	None		
Audit languages:	English	**Report Issue Date:**	
Report Author:	Roland Cooke	**Report revision:**	Rev. 0

3. AUDIT CRITERIA AND OBJECTIVES

The objectives of this audit were:

- to confirm that the quality management system and technical documentation (where appropriate) conform with the requirements of the audit criteria and regulatory requirements of the standards listed in section 0 and/or (as applicable) requirements of the Manufacturer's own documented Quality Management System.
- to confirm that the organisation has effectively implemented the planned quality management system.
- to confirm that the management system is capable of achieving the organisation's policy objectives.
- to confirm the capabilities of the QMS to ensure compliance with applicable regulatory requirements.
- To upgrade certification to ISO13485:2016
- To perform initial MDSAP audit

4. SCOPE OF CERTIFICATION

Standard	Annex(es)	Accreditation Body	Certificate Number	Company Name	Scope
ISO13485:2016	n/a	UKAS	US02/56960	Ortho Technology, Inc.	Design, Manufacture, and Distribution of Orthodontic systems; brackets, bands, wires, appliances, adhesives, auxiliaries, accessories, dental burs, diamond discs and other orthodontic devices.
93/42/EEC	Annex II	CE 0120	US02/56962	Ortho Technology, Inc.	Orthodontic brackets, bands, components, elastomeric products, dental instruments, orthodontic wires, spring and attachments, dental burs and diamond discs, lingual retainers, bonding agents / adhesives, and gel etchants.

The client has confirmed that the name(s) and address(s) of the organization and the audit scopes (including translations if applicable) in this report are that required on the certificate (s) to be issued or continued	Yes
Has the preliminary scope or type of certification shown in proposal documents been changed? or has the existing certificate scope(s) been changed ? (see Section 7 - Administration)	Yes
Is this a multi-site audit? if Yes, All relevant sites and/or remote locations agreed with the client must be listed on the Audit Planning Matrix and each site address must be listed in the Scope of Certification section above	No

Note : Only the main address will be shown on the front page of the certificate, with additional sites on subsequent pages.

5. AUDIT FINDINGS

Stage 1 Audit or QMS Documentation Review Findings	
The organisation had previously had quality system management documentation reviewed against the audit criteria and the findings reported in a separate Stage 1 report	No
All issues raised in a Stage 1 report had been subsequently satisfactorily addressed unless raised as a nonconformity in this report.	

Audit Details - Opening and Closing Meetings
The audit started with a meeting attended by senior representatives of the organisation, where the audit criteria, scopes and auditing roles and processes of SGS were outlined. The audit concluded with a meeting attended by senior representatives of the organisation where the audit team presented their findings and recommendations and certificates details and scopes were agreed. It was confirmed if there have been any significant changes in the quality system since the last audit that have not been reported to SGS in the Pre-Audit Questionnaire (PAQ) or the Change Notification Form prior to the audit. Clients are reminded that all significant changes should be notified to SGS either in a Change Notification Form or PAQ. The procedure for corrective action plans and corrective actions was explained. Products and processes were sampled in this process based audit to represent the different relevant technologies, risks and objectives involved and to represent the different regulations covered by the audit. The audit methods used were interviews, observation of activities and review of documentation and records. The structure of the audit was in accordance with the audit plan and audit planning matrix included as annexes to this summary report. If further audit trail details are contained in audit notes and checklists, these do not form part of the report available to the organisation.

Opening & Closing Meeting Attendees			
Name	**Position**	**Opening Meeting**	**Closing Meeting**
Colleen Boswell	Director, RA/QA	Y	Y
Lauren Tiller	Associate RA Specialist	Y	Y
Jason Bourque	Marketing Manager	Y	Y
Anne Oliver	Product Manager	Y	Y

Maria White	Global CS Manager	Y	Y
Monica Aleman	QA Specialist	Y	Y
Lynn Cameron	Senior Manager, Distribution	Y	Y
Shelly Forcke	HR Manager	Y	Y
Shawn Potter	Director (General Manager)	Y	
Thomas Swan	Quality Systems Associate Manager	Y	Y
Kim Ramer	Purchasing Manager	Y (phone)	Y(Phone)

This audit included:	
Management Review, Planning and Objectives, Changes, Legal Requirements, Feedback, Internal Audit, Improvement and Corrective Actions including for post-market surveillance, Complaints, Certification Claims and Use of Marks	Yes
Management	Yes
Design and development	Yes
Production and process control	Yes
Purchasing control	Yes
Documentation and records	Yes
Customer related processes	Yes
Product technical documentation (Regulatory Technical Review)	No

Technical Documentation review
Where product Technical Documentation (technical files) were reviewed on site or off site as part of this audit, as a Notified Body or Hong Kong Medical Device Control Office recognised CAB, the files reviewed are listed below:
No TFs reviewed as part of this audit

6. ADDITIONAL INFORMATION

Additional Information about the Manufacturer	
Product types and Regulatory Markets with Classification	Products and classifications in EU and Canada Nickel Titanium Archwire – HC Class 2 (licence 61407), MDD Class IIa Bonding Agents/Adhesives – HC Class 2 (licence 61408), MDD Class IIa Composite Orthodontic Brackets – HC Class 2 (licence 61409), MDD Class IIa

	Ceramic Orthodontic Brackets – HC Class 2 (licence 61410), MDD Class IIa Stainless Steel Orthodontic Brackets, Bands, Attachments – HC Class 2 (licence 61411), MDD Class IIa Stainless Steel Archwire, Ties & Springs – HC Class 2 (licence 61412), MDD Class IIa Dental Debonding Burs – HC Class 2 (licence 77809), MDD Class IIa Finishing Burs, Enamel Polisher – HC Class 2 (licence 78138), MDD Class IIa Bur (Metal Cutter) – HC Class 2 (licence 78139), MDD Class IIa Interproximal Diamond Bur – HC Class 2 (licence 78140), MDD Class IIa Double-sided Diamond Disc – HC Class 2 (licence 78141), MDD Class IIa Orthodontic Extraoral Headgear – HC Class 2 (licence 78248), MDD Class I Orthodontic Elastomeric Products – HC Class 2 (licence 88852), MDD Class IIa Copper Nickel Titamium Archwire – HC Class 2 (license 92365), MDD class IIa. Flat Titanium Dead / Soft Lingual Retainer Wire – HC Class 2 (license 96243), MDD Class IIA Microtech Plus Orthodontic Bracket – HC Class 2 (license 96244), MDD Class IIA Tru Ease Bite Corrector – HC Class 2 (license 97808), MDD Class IIA TruEase Rapid Palatal Expanders - HC Class 2 (already added to existing license 61411), MDD Class IIA (These devices have been placed into the restructured Technical File family “Intraoral Appliances”, currently identified under “dental brackets” on the SGS EC certificate scope)
Main markets or customers:	USA, Canada, EU, Asia, South America, Japan, Mexico, Singapore (distributors and dental professionals / dental laboratories)
Critical Processes	International distribution – packaging & Shipping, picking, receiving & shipping, sales, purchasing, design (of labels only). Global regulatory compliance

Information on Critical Subcontractor and Critical Suppliers:

Critical Subcontractors (those with substantial involvement with the design or manufacture of the device or regulatory compliance, including subcontractors for virtual manufacturers)	Ortho Technology employs a large number of finished devices manufacturers, these were previously accepted under the MDD OBL process. Per the ending of that option in mid-2017, all the current manufacturers are now considered as critical subcontractors and have been moved into this section. In addition, medium risk product subcontractors that don't market to Europe have been added to this section. Each subcontractor is controlled under OT's supplier approval programme, vendors typically hold QMS certification. Each subcontractor is managed via a standardised quality agreement. Received product is controlled by incoming inspection processes (review of Certificate of Conformance, or dimensional / visual / functional testing as appropriate). Individual products may achieve Dock To Stock status, based on strong previous history of delivery quality. Aditek, Rua Cesario Mota 14 Cravinhos, Brazil 14140 – Brackets, MDD 93/42/EEC Annex II excl sec 4 with SIQ (NB 1304), expires 12th December 2021. Aditek hold ISO13485:2003 from PreSafe, certificate 213147-2017-AQ-BRA-NA-PS valid through February 2019. American Orthodontics 3524 Washington Ave Sheboygan, WI 53081 – Lingual Appliances, ISO13485:2016 from UL certificate number 1727.180905 valid through 04 Sept 2021. Holds MDSAP certificate 1728.180905 valid through 04 Sept 2021. CDB Corp 2304 Merchantile Dr, Leland, NC 28451 – Composite Brackets/Ceramic Brackets, MDD 93/42/EEC Annex II excl sec 4 with BSI, expires 4/20/23, certificate CE 534469 Hubit Company LTD #408 ABI, 752 IL-dong Sangrok-gu Ansan-shi Gyeonggi-do 425701 Korea – Ceramic Brackets/Stainless Steel Orthodontic Brackets/Bands/Attachments, ISO 13485 with Szutest, expires 2/24/2019, Certificate No. 31305701 MDD 93/42/EEX Annex II excluding section 4, expires 3/2/2021, Certificate No. 2195-MED-1306401 Dental Technologies 6901 North Hamlin Ave Lincolnwood, IL 60712 – Impression Supplies/Bonding Agents/Adhesives, MDD 93/42/EEC Annex II excl sec 4 with LNE, certificate 26838 rev 2 expires November 2019 ISO 13485 with LNE, expires 2/28/2019, Certificate No. 25482 Rev. 3

	Fortune Worldwide 6409 Cooper Place, Plano, TX 75093 – Attachments/Bands, MDD 93/42/EEC Annex II excl sec 4 with TUV SUD, expired August 2018. Ortho Technology no longer markets their products to the EU. Holds ISO13485:2003 from TUV Sud, certificate number Q1N 16 06 58658 008, valid through 31 July 2019 Glenroe Technologies/Raintree Essix 7290 26th Court East, Sarasota, FL 34243 – Elastomeric Products, ISO 13485 MDSAP with SGS, expires 04/02/2020 (recert 12/1/2018), Certificate No. US17/81826839 MDD 93/42/EEC Annex II excluding section 4 with SGS, expires 9/27/2021 (recert 3/1/2020), Certificate No. US13/82924.00 Komet USA 3042 Southcross Blvd, Suite 101 Rock Hill, SC 29730 – Burs and Discs, MDD 93/42/EEC Annex II excl sec 4 with TUV Rheinland, certificate number HD 60091372 0001, expires January 2019. These are the distributor for: Gebr. Brasseler GmbH & Co KG, Trophagener Weg 25, 32657 Lemgo, Germany. Hodls ISO13485 from TUV Rheinland, certificate SX 60116256 0001 expires March 2019 Maverick Dental LLC 1615 Golden Mile Hwy, Monroeville, PA 15146 – Burs and Discs, importer for EVE, Prima, and DFS. EVE holds ISO13485:2003 from mdc, certificate number D1319500005 valid through September 2019 Prima Dental holds ISO13485:2003 from LRQA, certificate number LRQ 4009561/F, valid through 31 March 2019 DFS-Diamon holds ISO13485:2003 from DQS, certificate number 170649395, valid through September 2019 Septodont 4 16 South Taylor Avenue Louiville, CO 80027 Dental bonding agents and adhesives (finished devices) MDD 93/42/EEC Annex II excluding Section 4 with BSI, expires 1/20/2023, Certificate No. CE 683658 ISO 13485 with BSI, expires 12/31/2018, Certificate No. FM 677726 Ortho Organizers 1822 Aston Carlsbad, CA 92008 – Attachments/Bands, ISO 13485 with Presafe, expires 2/28/2019, Certificate No. 247309-2017-AQ-NOR-NA-PS Rev. 0.0 MDD 93/42/EEC Annex II excluding Section 4, expires 4/1/2023, Certificate No. 245818-2017-CE-NOR-NA-PS Rev. 4.0 Ultimate Wireforms, 200 Central Street, Bristol, CT 06010 – Wire Products – Nickel Titanium Archwire, MDD 93/42/EEC Annex II excl sec 4 with BSI, Certificate No. CE 613829 expires 17 Sept 2023. ISO 13485 with BSI, expires 2/28/2019, Certificate No. MD 613830 World Class Technology 1300 NE Alpha Dr, Mcminnville, OR 97128 – Attachments/Bands,

	ISO 13485 with TUV Austria, expires 4/30/2020, Certificate No. TUV-A-MT-1/15/E222 MDD 93/42/EEC Annex V with TUV Austria, expires 4/30/2020, Certificate No. TUV-A-MT-1/15/QP093 Ortho Technology is not selling these products to the EU. G&H Wire Company - 2165 Earlywood Drive, Franklin, IN 46131 Holds MDD Annex V from BSI, certificate CE 635654, valid through October 2022 Orthodontic Manufacturer SIA srl: palatal expanders (see later). Four product codes Zona Industriale snc 81050 Rocca d'Evandro, CE Italy Quality Agreement signed 11th April 2017 Holds EC Annex II certification from Cermet (CE 0476), valid through November 2019 ISO 13485 with Kiwa, expires 2/28/2019, Certificate No. 11401-M MDD 93/42/EEC with CERMET Annex II excluding section 4, expires 11/2/2019, Certificate No. MED 31222
Critical Suppliers	None

Follow-up of Previous Audit Results:	
The results of the last audit of this quality management system (SGS or previous certification body) have been reviewed, in particular to assure appropriate corrective and preventative action has been implemented to address any nonconformity identified. This review has concluded that :	
Any nonconformity identified during previous audits has been corrected and the corrective action continues to be effective and no issues have been raised as new nonconformities.	Yes
N/A indicates that no CARs were raised on the previous audit or this was an unscheduled visit and CARs were not reviewed.	

Follow-up on this Audit of Specific Issues:
Per V3 audit report, validation controls and internal audit controls were assessed in depth. No specific issues from PAQ, vigilance or recalls NOCs relating to vendors SIA Orthodontics, J&J Instruments, and Aditek were followed up. NOC relating to address change to EU Representative was followed up.

7. AUDIT CONCLUSIONS

Non-Conformities:				
Number of nonconformities identified (CARs):	**Major**	4	**Minor**	15
Number of Technical File review nonconformities identified (TCARs):	**Major**	n/a	**Minor**	n/a

Correction Action Requests (CAR), detailing any identified nonconformities and the required corrective action plans are attached to this report as appendices.
All nonconformities detailed shall be addressed through the organization's corrective action process, in accordance with the relevant corrective action requirements of the audit standard, including actions to prevent recurrence, and complete records maintained.
There are two possible options for close out of any Major nonconformities identified as shown below :

On-Site Closure of Major CAR – within 90 days Corrective actions to address the identified Major nonconformities shall be carried out **immediately** and SGS notified of the actions taken **within 30 days**. An SGS auditor will perform a **follow up audit on site at an agreed date,** to confirm the actions taken, evaluate their effectiveness, and determine whether certification can be granted or continued. The audit and acceptance of closure of the nonconformities must be completed **within 90 days**	N/A
Off-Site Closure of Major CAR – within 90 days Corrective actions to address the identified Major nonconformities shall be carried out **immediately** and the **supporting evidence must be sent to the SGS auditor** for **off-site** review. The acceptance and closure of the nonconformities must be completed **within 90 days**, on an **agreed date**.	Yes

Please note: 90 days is the total time limit allowed for completion of the process to close out Major non-conformities, including submission of evidence, review and acceptance by the auditor, and of the independent certification review and certification decision. If the process is not completed with 90 days, new certificates cannot be issued and current certificates may be suspended, or a device removed from the certificate scope. At the next scheduled audit visit, the SGS audit team will follow up on **all** identified nonconformities to confirm the effectiveness of the corrective actions taken. The organisation was reminded that delays in submission of corrective action plans and implementation of corrective actions for Major CARs will delay certification by SGS.

Audit Obstacles encountered and Impact on Audit:

No obstacles were encountered that impact the reliability of the audit or the validity of the audit conclusions.

Any other specific audit details including:
Any offsite advice or input: None
Corrections made during audit: None
Unresolved diverging opinions: None

Audit Conclusions - Effectiveness of quality system:
The audit team concludes that the organization has demonstrated the following based on the audit evidence: The organization was not able to provide sufficient evidence of effective implementation and maintenance/ improvement of its quality management system in all areas to meet its quality objectives and to demonstrate regulatory compliance, and major non-conformities have been raised in these areas.

Conformity with Audit Criteria and Objectives:

The audit team concludes for the audit criteria and objectives defined in Section 3 of this report and where Yes is indicated below that the organization has established and maintained its quality management system and technical documentation in line with the requirements of the following standards and regulations and demonstrated the ability of the system to systematically achieve agreed requirements for products within the scope and that any non-conformity raised has only been considered minor.

Standard	Annex(es)	Y/N
ISO13485:2016	n/a	N
93/42/EC	Annex II	N

Details of audit objective not met (if applicable):
Objectives were met

Audit Recommendations:

Therefore the audit team recommends that, based on the results of this audit, the system's demonstrated state of development and maturity and the demonstrated level of adequacy for the quality management system to systematically meet the agreed requirements certification be (insert X in the relevant cells)

	Granted	Continued	Withheld until satisfactory corrective action is completed	Suspended until satisfactory corrective action is completed	N/A
ISO 9001:2008 Initial/Current	☐	☐	☐	☐	☒
ISO 9001:2008 Extension to scope	☐	☐	☐	☐	☒
ISO 13485:2003 Initial/Current	☐	☐	☐	☐	☒
ISO 13485:2003 Extension to scope	☐	☐	☐	☐	☒
ISO 13485:2016 Initial/Current	☐	☐	☒	☐	☐
ISO 13485:2016 Extension to scope	☐	☐	☐	☐	☒
Directive 93/42/EEC Initial/Current	☐	☐	☒	☐	☐
Directive 93/42/EEC Extension to scope	☐	☐	☐	☐	☒
Directive 98/79/EC Initial / Current	☐	☐	☐	☐	☒
Directive 98/79/EC Extension to scope	☐	☐	☐	☐	☒

Hong Kong Medical Device Administrative Control System (HK MDACS) Initial/Current	☐	☐	☐	☐	☒
Hong Kong Medical Device Administrative Control System (HK MDACS) Extension to scope	☐	☐	☐	☐	☒

Audit Explanations:

SGS explained that:

- Auditing was a sampling activity and that consequently problems might exist that were not detected on this audit.
- Information obtained during the audit would be treated in confidence with the proviso that certain information could be disclosed to Regulatory Bodies where allowed under the relevant regulations.
- The organisation had an obligation to inform SGS of any proposed significant change in the quality management system or scope of certification.
- The certification was based on the activities and information shown in the Audit Summary above and that changes may represent significant changes in the quality management system or scope.
- The certification was based on the activities and information shown in the Audit Summary above and that changes may represent significant changes in the quality management system or scope.
- The organisation had confirmed that no animal products or medicinal products were used in the manufacture or incorporated into the devices unless disclosed previously.
- MDD 93/42/EEC covers all the current amendments including 2007/47/EC.
- Where appropriate Class III devices under Directive 93/42/EEC could not be placed on the market without a valid EC Design Examination certificate (Annex II section 4).
- Where appropriate List A devices under Directive 98/79/EC could not be placed on the market without a valid EC Design Examination certificate (Annex IV section 4) and without satisfactory arrangements for ongoing batch verification.
- The client should note that the list of critical subcontractors in Section 6 is the list that will be used for Unannounced Audit planning for EU Directive certification. If they are changes to the sub-contractors, and in particular the actual Manufacturing Site address, which is different to that listed, please inform the Notified Body of the change.

SGS explanation of certification process:

- At the conclusion of this audit, the lead auditor will have made an audit recommendation. The audit documentation is then submitted for an independent technical and certification review, as defined under accreditation or designation requirements. All Major CAR and any clarification on the audit documentation must be closed before final approval is granted, and before any certificate, if relevant, is issued.

8. ADMINISTRATION

Is there a need to issue a new or changed certificated now?	No
Will there a need to issue a new or changed certificate after major CAR close out?	Yes
An unscheduled audit was agreed with the organisation due to immaturity in the quality management system or the number and nature of the non-compliances – see additional comments for details agreed with client.	No
An extended next scheduled audit was agreed with the organisation	Yes
Consideration of increased frequency of unannounced audit recommended as per 2013/473/EU Annex III.1	No

New proposal required – see additional comments for details	No
Major/Minor CAR has been raised with special conditions for acceptance and verification that requires a reviewer with specific complex codes. SGS office required to add note on system, for auditor/expert required for CAR close out.	No
The certification scope has been reworded or the certificate type has been changed as recommend in Section 4 "Scope of Certification and explained below, and must be used for certificate issue.	Yes

Explanation for change to initial proposed scope or current certification scope:
Upgrade to ISO13485:2016

Additional comments and further actions for SGS Administration:
For Close out of CARs Documentation to show correction and corrective action to be sent to Roland Cooke no later than 01st December 2018 for close out on 14th December 2018. The minimum anticipated time is 1.0 days but may be longer and will be invoiced accordingly. The client should note that the certificate is at risk of being suspended or a device being removed from the certification scope, if there is insufficient evidence to fully close the Major CARs on the scheduled close out date. **For CAR plans:** It was agreed that the Corrective Action Plan for CAR forms 1-19 would be completed and returned to Roland Cooke by 20th September 2018

9. NEXT AUDIT

Additional Comments or Areas for follow up at next audit for SGS Auditor:
2.0 days to be added to next audit to close out 15 Minor CARs

10. FINAL DECLARATION BY LEAD AUDITOR

All members of the audit team confirmed their compliance with the SGS Code of Integrity and Professional Conduct and specifically with the SGS Medical Device Impartiality and Conflict of Interest Statement.
The lead auditor confirms and declares on their own behalf and for all on site audit team members that there is no conflict of interest in performing this audit:
Lead Auditor acknowledged: ☒

Contact with the approved/accredited certification body can be made via the following :
SGS United Kingdom Limited: 202b, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom
E-mail: globalmedical@sgs.com

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