

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

G&H Wire Company, Inc
dba Highland Metals Inc., Flexmedics,
OrthoClub, G&H Orthodontics,
Orthodontic Design & Production
40 Linville Way
Franklin
Indiana
46131
USA

Facility ID Number: F001963

Holds Certificate No:

MDSAP 695170

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

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-02-03

Effective Date: 2025-10-04

Expiry Date: 2028-10-03



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 695170**

Registered Scope:

Design, manufacture and distribution of orthodontic archwires, brackets, bands, tubes, hooks, springs, intraoral and extra-oral elastics bands, elastic chain, elastomeric ligatures, ligatures ties, kobayashi hooks, orthodontic appliances and orthodontic accessories.

Distribution of orthodontic appliances and orthodontic accessories.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.