

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
2165 Earlywood Drive
Franklin
Indiana
46131
USA

Facility ID Number: F001963

Holds Certificate No:

MDSAP 695170

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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

Distribution of orthodontic appliances and orthodontic accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-02-03

Effective Date: 2021-10-26

Expiry Date: 2022-10-03



BSI Group America Inc. is an MDSAP authorized auditing organization

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