



## Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

Holds Certificate Number: MD 635659

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following 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, appliances and accessories.

Distribution of orthodontic appliances and orthodontic accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-07-21

Latest Revision Date: 2022-09-28

Effective Date: 2022-10-04 Expiry Date: 2025-10-03

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...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory