

Certificate of Registration

QUALITY 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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