

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
2165 Earlywood Drive
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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-07-21

Latest Revision Date: 2021-06-27

Effective Date: 2021-06-27

Expiry Date: 2022-10-03



Page: 1 of 1

...making excellence a habit.™