



Certificate No. 2582-3-2016

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from March 21, 2016 to March 20, 2018.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Corporate Headquarters

G&H Wire Company
2165 Earlywood Drive
Franklin, IN USA 46131

Name of Manufacturer

Highland Metals Inc.
2165 Earlywood Dr
FRANKLIN, IN USA 46131

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Name of Corporate HeadquartersG&H Wire Company
2165 Earlywood Drive
Franklin, IN USA 46131Name of ManufacturerHighland Metals Inc.
2165 Earlywood Dr
FRANKLIN, IN USA 46131Name of Product(s)

Orthodontic Wires
Orthodontic Springs
Orthodontic Hooks
Orthodontic Ligatures
Orthodontic Elastomeric
Beta Blue Arches - Lingual form: Sizes .016, .016x.016, .016x.022, .017x.025, .018x.018
Beta Blue Arches - Natural, Progressive or Youth forms: Sizes .016, .018, .016x.016,
.016x.022, .017x.025, .018x.018, .018x.025, .019x.025, .021x.025
Beta Blue Straight Lengths: Sizes .016, .018, .016x.016, .016x.022, .017x.025, .018x.018,
.018x.025, .019x.025, .021x.025
Broussard NiTi Teardrop Spring (.012): Size 66mm
Elastic Ligature Ties, Chain Elastic (15' spool):
(Both products available in the following colors):
Black, Blue, Clear, Gold, Green, Grey, Pink, Purple, Red, Silver, Teal, Tooth, White,
Yellow, Smoke, Light Sky Blue, Royal Blue, Navy Blue, Glow Blue, Lavender, Transparent
Green, Neon Green, Glow, Fluorescent Orange, Orange, Fluorescent Pink, Fuschia, Maroon,
Metallic Blue, Metallic Red, Pearl, Pearl Blue, Pearl Green
(Ties also in): Rainbow Combo, Assorted Combo, Vibrant Combo
Endurance Chain Elastics: clear or grey
Heat Activated NiTi Arches - Natural or Progressive forms: Sizes .014, .016, .018, .020,
.014x.025, .016x.016, .016x.022, .016x.025, .017x.025, .018 x.018, .018x.025, .019x.025,
.020x.020, .021x.025
Heat Activated NiTi High Torque Arches - Broad, Natural or Progressive forms: Sizes
.016x.022, .017x.025, .019x.025, .021x.025
Heat Activated Reverse Curve NiTi - Natural or Progressive forms: Sizes .016, .018,
.016x.016, .016x.022, .017x.025, .018x.025, .019x.025, .021x.025
High Force NiTi Coil Springs - Closed Eyelet (9mm or 12mm): Sizes .010x.030, .011x.030
Kobayashi Tie Hooks - Short or Long: Sizes .012, .014
Nico Blue Retainer Wire: Sizes .032, .036
Nikodem NiTi Spring (.010"): Sizes 5mm, 9mm, 10mm, 12.5mm, 14mm, 18mm
Nikodem Zero Spring (.010): Sizes TAD (Small), Bracket (Large)
NiTi Arch Wire - Spool - Heat Activated: Sizes .014, .016, .018, .020
NiTi Arch Wire - Spool - High Force: Sizes .012, .014, .016, .018, .020
NiTi Arch Wire - Spool - Regular Force: Sizes .012, .014, .016, .018, .020
NiTi Arch Wire - Spool - Ultimate Control: Sizes .012, .014, .016, .018, .020
NiTi Stop Wound Springs: Sizes .010x.036, .010x.045
Pre-Formed Ligature Wire - Long: Sizes .009, .010, .012, .014
Pre-Formed/Pre-Twist Ligature Wire .010
Stainless Steel 3-Strand Arch Wires - Natural form: Sizes .0155, .0175, .0195
Stainless Steel 3-Strand Spool: Sizes .0155, .0175, .0195
Stainless Steel 6-Strand Arch Wires - Natural form: Sizes .0155, .0175, .0195
Stainless Steel 7-Strand Spool: Sizes .0155, .0175, .0195
Stainless Steel 8-Strand Braided Arch Wires - Natural form: Sizes .016x.016, .016x.022,
.017x.025, .018x.025, .019x.025, .021x.025
Stainless Steel 8-Strand Braided Straight Lengths: Sizes .016x.016, .016x.022, .017x.025,
.018x.025, .019x.025, .021x.025
Stainless Steel Arch Wires - Natural, Progressive, Standard, Broad and Youth forms. Sizes





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.012, .014, .016, .018, .020, .014x.018, .014x.025, .015x.020, .016x.016, .016x.022, .016x.025, .017x.017, .017x.022, .017x.025, .018x.014, .018x.018, .018x.022, .018x.025, .019x.025, .020x.015, .020x.020, .021x.025, .021x.028

Stainless Steel Arch Wires - Lingual form. Sizes .014, .016, .018, .016x.016, .016x.022, .017x.025, .018x.025

Stainless Steel Ball Clasps: Sizes .024, .028, .032, .036, .040

Stainless Steel Half Round Clasps Wire: Sizes 12 Gauge .081, 14 Gauge .064, 15 Gauge .057, 16 Gauge .051

Stainless Steel High Tensile Arch Wires - Natural or Progressive forms. Sizes .012, .013, .014, .016, .018, .020, .014x.018, .014x.025, .015x.020, .016x.016, .016x.022, .016x.025, .017x.017, .017x.022, .017x.025, .018x.014, .018x.018, .018x.022, .018x.025, .019x.025, .020x.015, .020x.020, .021x.025

Stainless Steel Ligature Spool: Sizes .009, .010, .012, .014

Stainless Steel Retainer Wire: Sizes .028, .030, .032, .036

Stainless Steel Straight Lengths: Sizes .012, .014, .016, .018, .020, .016x.016, .016x.022, .017x.017, .017x.022, .017x.025, .018x.018, .018x.022, .018x.025, .019x.025, .021x.028

Stainless Steel Triangular Straight Lengths .030" x 6"

Super Elastic NiTi Hi-Torque Arches - Broad, Natural and Progressive forms. Sizes .016x.021, .017x.025, .019x.025

Super Elastic Regular Force NiTi - Natural, Progressive, Standard, Broad and Youth forms. Sizes 010, .012, .014, .016, .018, .020, .014x.018, .014, .025, .016x.016, .016x.022, .016x.025, .017x.017, .017x.022, .017x.025, .018x.014, .018x.018, .018x.022, .018x.025, .019x.025, .020x.020, .021x.016, .021x.025, .021x.028, .022x.016

Super Elastic Regular Force NiTi - Lingual form: Sizes .012, .014, .016, .018, .016x.022

Super Elastic NiTi Coil Spring - Closed - Spool: Sizes .007x.030, .008x.030, .009x.030

Super Elastic NiTi Coil Spring - Closed Eyelet (9mm or 12mm): Sizes .010x.030, .011x.030

Super Elastic NiTi Coil Spring - Open - Spool: Sizes .010x.030, .012x.030, .012x.036

Super Elastic NiTi Coil Spring - Open (3x7"): Sizes .010x.030, .012x.030, .012x.036

Super Elastic NiTi Intrusion - Natural form: .014, .016, .018, .020, .016x.016, .016x.022, .017x.025, .018x.018, .018x.025, .019x.025, .021x.025

Super Elastic Reverse Curve NiTi - Natural or Progressive forms: Sizes .014, .016, .018, .020, .016x.016, .016x.022, .017x.025, .018x.018, .018x.025, .019x.025, .021x.025

Tomas NiTi Spring (.010"): Sizes 7mm, 11mm, 14mm

Triangular Clasp Wire .030" x 1.5"

-----END OF PRODUCT LIST-----

