

## Declaration of Conformity

**Manufacturer:** Rocky Mountain Orthodontics, Inc. (RMO, Inc.)  
**Address:** 650 W. Colfax Ave.  
 Denver, Colorado 80204  
  
**Device:** Orthodontic Appliances

Designation:	GMDN Code	EU Classification
Bimetric Arch	41397	Ila (Annex IX, rule 5)
Lingual Arch	41397	Ila (Annex IX, rule 5)
Rapid Palatal Expanders	35310	Ila (Annex IX, rule 5)
Quad Helix	41397	Ila (Annex IX, rule 5)
Multi-action Appliance	41397	Ila (Annex IX, rule 5)
Palatal Appliance	41397	Ila (Annex IX, rule 5)
Distalizing Arch	41397	Ila (Annex IX, rule 5)
Mesial/Distal Arch	41397	Ila (Annex IX, rule 5)
Orthopedic Incline	33592	Ila (Annex IX, rule 5)
Tongue Retainer	33592	Ila (Annex IX, rule 5)
Space Maintainer	31754	Ila (Annex IX, rule 5)
Appliance Accessories	41397	Ila (Annex IX, rule 5)

**European Representative:** RMO Europe  
 300 Rue Geiler de Kaysersberg  
 67400 Illkirch, France

**Notified Body:** mdc Medical Device Certification GmbH  
 Kriegerstraße 6  
 70191 Stuttgart, Germany  
 Identification Number: 0483

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This Declaration of Conformity has been issued from Denver, CO and it expires on October 31, 2021.

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 Tony Zakhem  
 Chairman/CEO

  
 Location

  
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**Device:** Orthodontic Elastics

Designation:	GMDN Code	EU Classification
Elastics	62704	Ila (Annex IX, rule 5)
Energy Chain	62703	Ila (Annex IX, rule 5)
Ligatures	41677	Ila (Annex IX, rule 5)
Separators	42340	Ila (Annex IX, rule 5)
Tie Thread	62074	Ila (Annex IX, rule 5)
Superthread	62074	Ila (Annex IX, rule 5)
Elastic Ligature Thread	41677	Ila (Annex IX, rule 5)

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Device: **Dual Top Anchor System**

Dual Top Anchor System	42347	Ib (Annex IX, rule 8)
Endosseous Implants	42347	Ib (Annex IX, rule 8)
Mini-Orthodontic Implant Pilot Drill	36235	Ia (Annex IX, rule 6)
Orthonia Driver	33968	Ia (Annex IX, rule 9)
Dual Top Manual Drivers/Attachments	33968	I (Annex IX, rule 6)

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**Manufacturer:** Rocky Mountain Orthodontics, Inc. (RMO, Inc.)  
**Address:** 650 W. Colfax Ave.  
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**Device:** Orthodontic Wires

Designation:	GMDN Code	EU Classification
Wire	16204	Ila (Annex IX, rule 5)
Braided Wire	16204	Ila (Annex IX, rule 5)
Straight Wire	16204	Ila (Annex IX, rule 5)
Ligature Wire	41677	Ila (Annex IX, rule 5)
Arch Wire	41397	Ila (Annex IX, rule 5)
Springs; Coil, Compression, Extension, Retractor, Torquing Retainer	31797	Ila (Annex IX, rule 5)
Clasps	35310	Ila (Annex IX, rule 5)
Coated Arch Wire	16204	Ila (Annex IX, rule 5)
Wire Accessories	41397	Ila (Annex IX, rule 5)
Solder Wire	16204	Ila (Annex IX, rule 5)
	38799	Ila (Annex IX, rule 5)

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 300 Rue Geiler de Kayzersberg  
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## Declaration of Conformity

**Manufacturer:** Rocky Mountain Orthodontics, Inc. (RMO, Inc.)  
**Address:** 650 W. Colfax Ave.  
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**Device:** Orthodontic Aesthetic Brackets

Designation:	GMDN Code	EU Classification
Signature III	58937	Ila (Annex IX, rule 5)
FLI Clear	58937	Ila (Annex IX, rule 5)
Alice	46582	Ila (Annex IX, rule 5)
Alpine Clear SL	58937	Ila (Annex IX, rule 5)
Bracket Accessories	58937	Ila (Annex IX, rule 5)

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 300 Rue Geiler de Kaysersberg  
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**Manufacturer:** Rocky Mountain Orthodontics, Inc. (RMO, Inc.)  
**Address:** 650 W. Colfax Ave.  
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**Device:** Orthodontic Metal Brackets

Designation:	GMDN Code	EU Classification
Synergy	46581	Ila (Annex IX, rule 5)
Synergy FX	46581	Ila (Annex IX, rule 5)
Synergy R	46581	Ila (Annex IX, rule 5)
Mini Taurus	46581	Ila (Annex IX, rule 5)
Integra	46581	Ila (Annex IX, rule 5)
FLI Twin	46581	Ila (Annex IX, rule 5)
iTTR	46581	Ila (Annex IX, rule 5)
Altitude SL	46581	Ila (Annex IX, rule 5)
Mini Low Profile	46581	Ila (Annex IX, rule 5)
Alpine SL	46581	Ila (Annex IX, rule 5)
Other Brackets	46581	Ila (Annex IX, rule 5)
Bracket Accessories	46581	Ila (Annex IX, rule 5)

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Device: **Adhesives: Orthodontic**

Designation:	GMDN Code	EU Classification
Trulock Primer Activated Adhesive	31750	Ila (Annex IX, rule 5)
Trulock Light Activated Adhesive	31750	Ila (Annex IX, rule 5)
Trulock Primer	31750	Ila (Annex IX, rule 5)
Trulock Bonding Resin	31750	Ila (Annex IX, rule 5)
Trulock Etchant Liquid / Gel	36153	Ila (Annex IX, rule 5)
Trulock Conditioners	36153	Ila (Annex IX, rule 5)
TruLock Band Adhesive	31750	Ila (Annex IX, rule 5)
TruLock Light Activated Flowable Adhesive	31750	Ila (Annex IX, rule 5)

**Adhesive Accessories:**

Dispensing Gun (for Adhesive Capsules)	16196	I (Annex IX, rule 1)
Spatula	38530	I (Annex IX, rule 1)
Brushes	35697	I (Annex IX, rule 5)
Replacement Tips		I (Annex IX, rule 5)
FlashMax P4 Light Pen and accessories	33968	I (Annex IX, rule 5)
Paste Applicators		

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**Device:** Orthodontic Bands and Prewelds

Designation:	GMDN Code	EU Classification
Bands	38734	Ila (Annex IX, rule 5)
Seating Lug	46338	Ila (Annex IX, rule 5)
Preweld	46338	Ila (Annex IX, rule 5)
Preweld Attachments	46338	Ila (Annex IX, rule 5)

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**Manufacturer:** Rocky Mountain Orthodontics, Inc. (RMO, Inc.)  
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**Device:** Orthodontic Tubes

Designation:	GMDN Code	EU Classification
Buccal Tubes	31759	Ila (Annex IX, rule 5)
Lingual Tubes	31759	Ila (Annex IX, rule 5)
Self-Ligating Buccal Tubes	31759	Ila (Annex IX, rule 5)
Lingual Post	31759	Ila (Annex IX, rule 5)
Lingual Sheath	31759	Ila (Annex IX, rule 5)

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