

## Declaration of Conformity

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

**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

RMO, Inc. has implemented and maintains a Quality Management System which is certified by mdc. RMO, Inc. declares under its sole responsibility that all products listed above conform to the applicable requirements of:

- Annex II (excluding section 4) of the Council Directive 93/42/EEC (Registration no. D1007800027)
- FDA Quality System Regulations
- Canadian Medical Device Regulations (CMDR)

RMO, Inc. also declares that all products listed are in conformity with the Essential Requirements of Annex I and the provisions of Council Directive 93/42/EEC Annex II, and conforms to harmonized standard ISO 13485.

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

A Technical Information File for these products is located at Rocky Mountain Orthodontics, Inc. 650 W. Colfax Ave. Denver, Colorado U.S.A. 80204.

RMO, Inc. as manufacturer is exclusively responsible for the Declaration of Conformity.

  
 Tony Zakhem  
 Chairman/CEO

  
 Location

  
 Date

