

## **Declaration of Conformity**

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

**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)

**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

