Declaration of Conformity

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

Device: **Orthodontic Products**

Designation:	GMDN Code	EU Classification
Mouthguard	38621	I
Pliers, Instruments and Accessories	33209	I
Holder; Bracket, Needle	32886	I
Wrench; Hex, RM Lock	33968	I
Instruments for Bands and Accessories	31801	I
Mosquito Hemostat	32886	I
Cutters, Instruments and Accessories	32885	I
Tucker Tier	37413	I
Bite Block	16205	I
Tweezers, Direct Bond	32886	I
Scaler	35320	I
SL Instrument	62086	I
Cheek Retractors	44828	I
IPR Strip	35702	I
Miscellaneous Instruments and Accessories		I
Facebow	40468	I
Headgear	31757	I
Head Strap	31757	I
Spring Gear	31757	I
Orthopedic Face Mask	31757	I
Lip Bumper	31757	I
Modules	31757	I
Neck Pad		I
Ortho-Jel Alginate	35863	I
Impression Tray	16350	I
RMbond Model Box	10532	I
RMbond Thermoform Sheets	35863	I
Dispensing Gun (for Adhesive Capsules)	16196	I
Spatula	38530	I
Brushes	35697	I
Replacement Tips		I
FlashMax P4 Light Pen and Accessories	33968	I
Paste Applicators		I
Dual Top Manual Drivers/Attachments	33968	I
Patient Relief Wax	45251	I

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®
rocky mountain orthodontics™

RMO, Inc. has implemented and maintains a Quality Management System which is certified by mdc (CE Certificate# D1007800027, ISO 13485 Certificate# D1007800026). RMO, Inc. declares under its sole responsibility that all products listed above conform to the applicable requirements of:

- MDR European Medical Device Regulation 2017/745 Annex X
- FDA Quality System Regulations
- EN ISO 13485:2016
- Canadian Medical Device Regulations (CMDR)

This Declaration of Conformity has been issued from Denver, Colorado, USA.

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

Brandon Bernacchi Digitally signed by Brandon Bernacchi
Date: 2021.06.30 13:53:15 -04'00'

Brandon Bernacchi
CEO