



RMO
2165 Earlywood Drive
Franklin, IN 46131
U.S.A

Date: 08/12/2024

To: Whom it May Concern

DECLARATION LETTER

I, Grace McColley, am authorized to execute this document on behalf of RMO. I hereby attest that all the Declarations of Conformities attached are true and correct.

I declare that the above statement is true and accurate to the best of my knowledge, information, and belief.

Sincerely,

Print Name: Grace McColley

Title: QA/RA Manager / Management Representative

Contact Telephone Number: 317-631-3613

Contact email: regulatory@rmortho.com

Acknowledgment for Individual

State of Indiana, County of Johnson I, a Notary Public, hereby certify that Grace McColley whose name is signed to the foregoing instrument or conveyance, and who is known to me, acknowledged before me on this day that, being informed of the contents of the conveyance, he/she/they executed the same voluntarily on the day the same bears date. Given under my hand this the 12th day of August, 2024.

(Seal, if any)

(Signature of notarial officer) Title (and Rank)

My commission expires: May 22, 2032



Declaration of Conformity

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

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)
iTRR	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)

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.

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 Zakem
 Chairman/CEO

 DENVER, CO
 Location

 9/22/2020
 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF010000 Orthodontic Metal Brackets Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmoeurope.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.12 10:03:09 -04'00'



Declaration of Conformity

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

Device: Orthodontic Tubes

<u>Designation:</u>	<u>GMDN Code</u>	<u>EU Classification</u>
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:

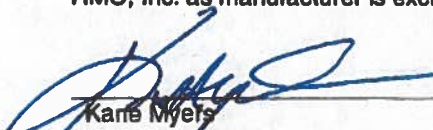
- Annex II (excluding section 4) of the Council Directive 93/42/EEC (Registration no. D1007800027)
- FDA Quality System Regulations
- Canadian Medical Device Regulations (CMDR)

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.

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.


 Karie Myers
 Vice President of Operations

Denver
 Location

4/12/21
 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF020000 Orthodontic Tubes Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmo europe.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.02 10:09:09 -04'00'



Declaration of Conformity

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

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)

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.

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 Zakheim
 Chairman/CEO


 Location


 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF010001 Orthodontic Aesthetic Brackets Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmo europe.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.12 10:22:06 -04'00'



Declaration of Conformity

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

Device: Orthodontic Appliances

<u>Designation:</u>	<u>GMDN Code</u>	<u>EU Classification</u>
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

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.

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 Zahem
 Chairman/CEO

Denver, CO
 Location

9/22/2020
 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF040000 Orthodontic Appliances Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmoeurope.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.12 10:23:16 -04'00'



Declaration of Conformity

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

Device: Orthodontic Bands and Prewelds

<u>Designation:</u>	<u>GMDN Code</u>	<u>EU Classification</u>
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)

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

Notified Body: mdc Medical Device Certification GmbH
 Kriegerstraße 6
 70191 Stuttgart, Germany

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.

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 Zalkem
 Chairman/CEO


 Location


 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF030000 Orthodontic Bands and Prewelds Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmoeurope.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.02 10:08:48 -04'00'



Declaration of Conformity

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

Device: Orthodontic Wires

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

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



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF050000 Orthodontic Wires Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@moeeurope.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.12 10:24:26 -04'00'



Declaration of Conformity

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

Device: Orthodontic Elastics

Designation:	GMDN Code	EU Classification
Elastics	62074	Ila (Annex IX, rule 5)
Energy Chain	62073	Ila (Annex IX, rule 5)
Ligatures	41677	Ila (Annex IX, rule 5)
Separators	44732	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)

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.

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.


 Kane Myers
 VP of Operations

Denver
 Location

11/29/20
 Date



ADDENDUM II: DECLARATION OF CONFORMITY

This addendum identifies the update to address, having relocated from Greenwood, IN. This change is not identified as a significant change according to article 120 (3) MDR.

Applicable DOC		
TIF090000 Orthodontics Elastics Declaration Sept 2020		
Manufacturer		
Name of Company	Address	Representative
RMO, Inc	2165 Earlywood Drive, Franklin, IN 46131 USA	Christine Cook PRRC / Management Representative
Authorized Representative		
Name of Company	Address	Telephone / email
RMO Europe	RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France	+33 (0)3 88 40 67 40 info@rmoeurope.com
Registration Information		
Notified Body	CE Certificate Number	
MDC Medical Device Certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany Identification Number: 0483	D1007800027	
Registrar	ISO 13485:2016 / MDSAP Certificate Number	
SGS NORTH AMERICA INC. 201 Route 17 North 7th and 8th Floors Rutherford, New Jersey, 07070 United States	US21/819944628	

Company Representative: Brian Dean
Title: Quality Manager

Signature / Date	
Brian Dean	Digitally signed by Brian Dean Date: 2022.05.02 10:10:11 -04'00'





Quality Form

DOCUMENT #: QP 7.3-1-F05	REVISION #: 03	CO #: 2022-077	DATE: 11/18/2022
------------------------------------	--------------------------	--------------------------	----------------------------

Title: Declaration of Conformity – MDR 2017/745 **Page 1 of 2**

- I. **Manufacturer:** RMO, Inc.
- II. **Address:** 2165 Earlywood Drive Franklin, IN 46131 (USA)
- III. **Single Registration Number (SRN):**US-MF-000034842
- IV. **The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.**
- V. **Authorized Representative:**
RMO Europe
300 rue Geiler de Kaysersberg
67411 Illkirch Cedex France


Single Registration Number (SRN): FR_AR_000003900

- VI. **Notified Body: (As Applicable to Class 1r, 1s, and 1m only)**
MDC Medical Device Certification GmbH
Kriegerstraße 6
70191 Stuttgart, Germany
Identification Number: 0483
- VII. **Quality System:** The quality management system of the manufacturer has been approved by the notified body MDC Medical Device Certification GmbH according to MDR European Medical Device Regulation 2017/745 Annex IX and EN ISO 13485:2016 compliant system.

CE Certificate #: D1007800027
EN ISO 13485:2016 Certificate: US21/819944628
Conformity Assessment Route: Annex IX (QMS and Technical Documentation)
- VIII. **Technical File No. and Name:** TECH 6 – Mouthguards and Patient Relief Wax
- IX. **Device Classification and Rule (Annex VIII):** I, Annex VIII Rule 5
- X. **Product(s):**

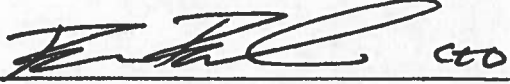
Description	Basic UDI-DI
Mouthguards	0885797CL1MouthguardLU
Patient Relief Wax	0885797WaxRC

- XI. **Applicable Standards & Common Specifications – Please reference the Applicable Regulations and Standards for a list of all applicable standards and common specifications.**

	Quality Form		
	DOCUMENT #: QP 7.3-1-F05	REVISION #: 03	CO #: 2022-077
Title: Declaration of Conformity – MDR 2017/745			Page 2 of 2

XII. Declaration of Conformity Effective Date:

We, the manufacturer, hereby declare that the medical devices, listed above conform to the applicable standards identified above and the provisions of MDR European Medical Device Regulation 2017/745 Annex IV.


 Signature / Brandon Bernacchi CEO

10-1-2023
 Date



Quality Form

DOCUMENT #:
QP 7.3-1-F05

REVISION #:
03

CO #:
2022-077

DATE:
11/18/2022

Title: Declaration of Conformity – MDR 2017/745

Page 1 of 6

I. Manufacturer: RMO, Inc

II. Address: 2165 Earlywood Drive Franklin, IN 46131 (USA)

III. Single Registration Number (SRN): US-MF-000034842

IV. The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

V. Authorized Representative:
RMO Europe
300 rue Geiler de Kaisersberg
67411 Illkirch Cedex France

Single Registration Number (SRN): FR_AR_000003900

VI. Notified Body: (As Applicable to Class 1r, 1s, and 1m only)
MDC Medical Device Certification GmbH
Kriegerstraße 6
70191 Stuttgart, Germany
Identification Number: 0483

VII. Quality System: The quality management system of the manufacturer has been approved by the notified body MDC Medical Device Certification GmbH according to MDR European Medical Device Regulation 2017/745 Annex IX and EN ISO 13485:2016 compliant system.

CE Certificate #: D1007800027
EN ISO 13485:2016 Certificate: US21/819944628
Conformity Assessment Route: Annex IX (QMS and Technical Documentation)

VIII. Technical File No. and Name: TECH 7 – Instruments and Impression Trays

IX. Device Classification and Rule (Annex VIII): I, Annex VIII Rule 5

X. Product(s):

Description	Basic UDI-DI
Aluminum Impression Trays	0885797Aluminumtrays5W
Disposable Impression Trays	0885797DisposabletraysS8
Ortho-Jel® Alginate	0885797Ortho-jel37

Description	Basic UDI-DI
Distalizing Arch Selector	0885797CL2AOrthoApplGS
Closing Loop Plier (Nose)	0885797CL1InstrumentsNZ



Quality Form

DOCUMENT #:
QP 7.3-1-F05

REVISION #:
03

CO #:
2022-077

DATE:
11/18/2022

Title: Declaration of Conformity – MDR 2017/745

Page 2 of 6

Description	Basic UDI-DI
Needle Holder Small Narrow Tip (Mathieu)	0885797CL1InstrumentsNZ
Needle Holder Small (Mathieu)	0885797CL1InstrumentsNZ
Hex Wrench	0885797CL1InstrumentsNZ
Three Jaw Banding Plier	0885797CL1InstrumentsNZ
FL® SL 3.0 Instrument for RMO® Self-Ligating Bracket	0885797CL1InstrumentsNZ
Instrument Rack	0885797CL1InstrumentsNZ
Flat and Hex Screwdriver	0885797CL1InstrumentsNZ
Band Adapter	0885797CL1InstrumentsNZ
Band Adapter Replaceable Bite Block	0885797CL1InstrumentsNZ
Closing Loop Plier (Standard)	0885797CL1InstrumentsNZ
How Plier Straight	0885797CL1InstrumentsNZ
How Plier Curved	0885797CL1InstrumentsNZ
Contouring Plier (Johnson)	0885797CL1InstrumentsNZ
Mosquito Hemostat	0885797CL1InstrumentsNZ
Crimpable Hook Plier	0885797CL1InstrumentsNZ
Contouring Plier (Gordon)	0885797CL1InstrumentsNZ
Wire Bending Plier Angle (Bird Beak Type)	0885797CL1InstrumentsNZ
Light Wire Plier	0885797CL1InstrumentsNZ
Ligature Tying Plier (Coon)	0885797CL1InstrumentsNZ
Nickel Titanium Crimping Plier	0885797CL1InstrumentsNZ
Three Jaw Clasp Adjusting Plier (Aderer Type) - up to 0.040"	0885797CL1InstrumentsNZ
Three Jaw Clasp Adjusting Plier (Aderer Type) - up to 0.030"	0885797CL1InstrumentsNZ
Heavy Wire Cutter	0885797CL1InstrumentsNZ
Ligature Tucker	0885797CL1InstrumentsNZ
Ligature Tucker and Tier (Broussard™)	0885797CL1InstrumentsNZ
Band Pusher	0885797CL1InstrumentsNZ
Posterior Band Removing Plier	0885797CL1InstrumentsNZ
Utility Scaling, Ligature Remover and Band Seating Instrument (Schure)	0885797CL1InstrumentsNZ
Three Step Loop Plier (Tweed)	0885797CL1InstrumentsNZ
Loop Forming Plier (Optical Type)	0885797CL1InstrumentsNZ
Posterior Band Removing Plier Replacement Pads	0885797CL1InstrumentsNZ
Band Pusher/Scaler (Guequierre)	0885797CL1InstrumentsNZ

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Description	Basic UDI-DI
Fitzgerald X-Ray Holding Unit Rubber Bite Block - Large	0885797CL1InstrumentsNZ
Fitzgerald X-Ray Holding Unit Rubber Bite Block - Small	0885797CL1InstrumentsNZ
Lingual Arch Forming Plier	0885797CL1InstrumentsNZ
Arch Forming Plier (Angle)	0885797CL1InstrumentsNZ
3D® Lingual Arch Selector	0885797CL2AOrthoApplGS
3D® Bimetric Arch Selector	0885797CL2AOrthoApplGS
3D® Maxillary Bimetric Distalizing Arch Selector	0885797CL2AOrthoApplGS
Penta-Morphic® Arch Selector	0885797CL2AOrthoApplGS
Cephalometric Tracing Template	0885797CL1InstrumentsNZ
Elgiloy® Hawley Retainer Gauge	0885797CL1InstrumentsNZ
Direct Bond Removing Plier - Narrow	0885797CL1InstrumentsNZ
Direct Bond Removing Plier - Wide	0885797CL1InstrumentsNZ
Two Step Loop Plier (Tweed)	0885797CL1InstrumentsNZ
Modular Omega Plier (RMO®)	0885797CL1InstrumentsNZ
Two Step Loop Plier Replacement Tips	0885797CL1InstrumentsNZ
Modular Omega Plier (RMO®) Replacement Tips	0885797CL1InstrumentsNZ
Distal End Cutter with Safety Hold - Regular Beak	0885797CL1InstrumentsNZ
Miniature Cutter	0885797CL1InstrumentsNZ
Ligature Cutter	0885797CL1InstrumentsNZ
Ligature and Hard Wire Cutter	0885797CL1InstrumentsNZ
Distal End Cutter with Safety Hold - Small Beak	0885797CL1InstrumentsNZ
Utility Plier (Weingard Style)	0885797CL1InstrumentsNZ
Cap Removal Instrument (RMO®)	0885797CL1InstrumentsNZ
Cap Removal Instrument (RMO®) Replacement Blades	0885797CL1InstrumentsNZ
Distal End Cutter Flush V Design	0885797CL1InstrumentsNZ
Distal End Cutter (Flush)	0885797CL1InstrumentsNZ
Flush Distal End Cutter with O-Ring - Short Cutter	0885797CL1InstrumentsNZ
Flush Distal End Cutter with O-Ring - Long Cutter	0885797CL1InstrumentsNZ
Flush Distal End Cutter Replacement O-Ring	0885797CL1InstrumentsNZ
Band Seater with Offset Tip	0885797CL1InstrumentsNZ
Band Seater Replacement Offset Tip	0885797CL1InstrumentsNZ



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Description	Basic UDI-DI
Band Seater Replacement Spring	0885797CL1InstrumentsNZ
Utility Plier (weingart Style - Mini)	0885797CL1InstrumentsNZ
Band Seater with Straight Tip	0885797CL1InstrumentsNZ
Band Seater Replacement Straight Tip	0885797CL1InstrumentsNZ
Band Seater with Narrow Straight Tip	0885797CL1InstrumentsNZ
Band Seater Replacement Narrow Straight Tip	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Single Sided Extra Fine	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Single Sided Fine	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Single Sided Regular	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Double Sided Extra Fine	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Double Sided Fine	0885797CL1InstrumentsNZ
Inter-Proximal Reduction (IPR) Strips - Double Sided Regular	0885797CL1InstrumentsNZ
Module Placing Plier	0885797CL1InstrumentsNZ
Direct Bonding Tweezer, Self-Locking w/ Thin Tips	0885797CL1InstrumentsNZ
Cap Removal Plier	0885797CL1InstrumentsNZ
Cap Removal Plier Replacement Blades	0885797CL1InstrumentsNZ
Ortho/Trace - Cephalometric Tracing Acetate	0885797CL1InstrumentsNZ
RMO® Instrument Lubricant	0885797CL1InstrumentsNZ
Loop Forming and Closing Plier (Nance Style) - Round	0885797CL1InstrumentsNZ
Maethieu Wide Tip	0885797CL1InstrumentsNZ
Methieu Hole-Tip	0885797CL1InstrumentsNZ
Mathieu Narrow Tip	0885797CL1InstrumentsNZ
Direct Bond Bracket Holder	0885797CL1InstrumentsNZ
How Plier - Straight - Round	0885797CL1InstrumentsNZ
Crimpable Hook Plier	0885797CL1InstrumentsNZ
Step Plier - 0.5mm	0885797CL1InstrumentsNZ
Step Plier - 1mm	0885797CL1InstrumentsNZ
Bird Beak Plier - Round	0885797CL1InstrumentsNZ
Cinch Back Plier - Round	0885797CL1InstrumentsNZ
NiTi Crimping Plier	0885797CL1InstrumentsNZ
3-Jaw Plier - Round	0885797CL1InstrumentsNZ




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Description	Basic UDI-DI
Wire Contouring Plier - Round	0885797CL1InstrumentsNZ
Stop/V-Bending Plier - Round	0885797CL1InstrumentsNZ
Posterior Band Remover	0885797CL1InstrumentsNZ
Posterior Band Remover Replacement Pads	0885797CL1InstrumentsNZ
Tweed Loop Forming Plier - Round	0885797CL1InstrumentsNZ
Tweed Loop Forming Plier Replacement Tip	0885797CL1InstrumentsNZ
Optical Plier - Round	0885797CL1InstrumentsNZ
Lingual Arch Forming Plier	0885797CL1InstrumentsNZ
Rectangular Arch Bending Plier (Tweed Style)	0885797CL1InstrumentsNZ
Synergy® Ligature Remover	0885797CL1InstrumentsNZ
Direct Bond Remover - Angled	0885797CL1InstrumentsNZ
Direct Bone Remover - Straight	0885797CL1InstrumentsNZ
Safety Hold Distal End Cutter - Round	0885797CL1InstrumentsNZ
Mini Pin and Ligature Cutter	0885797CL1InstrumentsNZ
Pin and Ligature Cutter	0885797CL1InstrumentsNZ
Hard Wire Cutter 2 - Round	0885797CL1InstrumentsNZ
Hard Wire Cutter - Round	0885797CL1InstrumentsNZ
Distal End Cutter with Long Handle - Round	0885797CL1InstrumentsNZ
Weingart Plier - Round	0885797CL1InstrumentsNZ
Standard Flush Cut and Hold Distal End Cutter - Round	0885797CL1InstrumentsNZ
Self-Ligating Instrument	0885797CL1InstrumentsNZ
Force Module Separator	0885797CL1InstrumentsNZ
Accessories Wrench	0885797CL1InstrumentsNZ
Cheek Retractors	0885797CL1InstrumentsNZ
Aligner Pliers	0885797CL1InstrumentsNZ
Arch Markers	0885797CL1InstrumentsNZ
Case Organizers	0885797CL1InstrumentsNZ
Alpine SL Opening Tool	0885797CL1InstrumentsNZ

XI. **Applicable Standards & Common Specifications** – Please reference the Applicable Regulations and Standards for a list of all applicable standards and common specifications.

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XII. Declaration of Conformity Effective Date:

We, the manufacturer, hereby declare that the medical devices, listed above conform to the applicable standards identified above and the provisions of MDR European Medical Device Regulation 2017/745 Annex IV.


 Signature / Brandon Bernacchi CEO

16-26-2023
 Date