



EU Quality Management Certificate



This is to certify that the company

RMO

2165 Earlywood Drive
Franklin, IN 46131
United States of America

SRN: US-MF-000034842

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of** **Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31620759 MDR2017Q
Certificate ID	1000190244
Effective date	2026-03-30
Expiry date	2031-03-29
Frankfurt am Main,	2026-03-30



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000034842
Certificate ID: 1000190244

Authorised Representative of the company:

RMO Europe

300 rue Geiler Kaysersberg.
Illkirch-Graffenstaden
67400 France

SRN: FR-AR-000003900

Device categories and variants covered by this certificate according to Article 52:

Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: Metal Brackets
Risk classification: IIa
Basic-UDI-DI: 0885797CL2AMetalBracketHK
Intended purpose: Orthodontic metal brackets are components of the orthodontic appliance system and support (hold) an archwire which applies the forces for the movement of teeth.

Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: Tubes
Risk classification: IIa
Basic-UDI-DI: 0885797CL2AOrthoTubeKY
Intended purpose: Orthodontic tubes are components of the orthodontic appliance system support an archwire which applies the forces for the movement of teeth.

Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: Bands
Risk classification: IIa
Basic-UDI-DI: 0885797OrthodonticBandsXS
Intended purpose: Orthodontic bands are components of the orthodontic appliance system and are typically used on the back molars for assisting in securing the archwire and other orthodontic components during treatment.

Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: Wires and Appliances
Risk classification: IIa
Basic-UDI-DI: 0885797CL2AOrthoApplGS
0885797CL2AOrthoWireL9
Intended purpose: Orthodontic wires (including archwires) and appliances are components of the orthodontic appliance system and are used in the treatment of malocclusion to support the movement of teeth.

Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: Aesthetic Brackets
Risk classification: IIa
Basic-UDI-DI: 0885797CL2AAestheticBrkUL
Intended purpose: Orthodontic aesthetic brackets are components of the orthodontic appliance system and support (hold) an archwire which applies the forces for the movement of teeth.



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Device category: **MDN1209 - Non-active non-implantable dental materials**
Product name: **Elastics**
Risk classification: **Ila**
Basic-UDI-DI: **0885797CL2AOrthoElasticAR**
Intended purpose: **Elastics are components of the orthodontic appliance system and are used to hold an archwire in a bracket or to exert force between other appliances used in the movement of teeth.**

Examinations and tests performed:

31620759 A215467MED 01 2025-03-14

31620759 A215466MED 02 "Orthodontic Metal Brackets" 2026-01-26

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
01	n/a	n/a	Initial