



# Accessories Product Technical Data Sheet

## SECTION 1: Identification of the Supplier of the Product Technical Data Sheet

<b>Manufacturer:</b> RMO 2165 Earlywood Drive Franklin, IN 46131 USA SRN #: US-MF-00003482 T 1-800-525-6735 <a href="mailto:customerservice@rmortho.com">customerservice@rmortho.com</a> <a href="https://rmortho.com/">https://rmortho.com/</a>	<b>U.S. Federal Register:</b> FDA Registration: 1718476
<b>Australian Sponsor:</b> AB Orthodontics PTY LTD 13/15 Collins St Melbourne VIC 3000 Australia T +61 3 9650 2526	<b>EU Representative:</b> RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex France SRN #: FR_AR_000003900 T +33 3 88 40 67 40 <a href="https://www.rmoeurope.com/">https://www.rmoeurope.com/</a>

## SECTION 2: RMO Orthodontic Accessories Products – Material Technical Information

Product Family	Material	Material Compliance Standard
<ul style="list-style-type: none"> <li>- Mouthguards</li> <li>- Patient Relief Wax</li> </ul>	Ethylene Vinyl Acetate Resin	ASTM D5594-98
	Microcrystalline Paraphin	ASTM 4924
	Petroleum Jelly	ASTM 4924
	Methyl Salicylate	ASTM 4924
Instruments and Impression Trays	Stainless Steel (302, 303, 304, 316L, 17-4, 410, 420)	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A580/A580M
	S125V High Corrosion Resistant Steel	ASTM A606
	Raw Mylar NPS	ASTM F2042
	Clear Plastic	ASTM D3935-21 ISO 11963:2012
	Silicone	ASTM F2042
	Zytel 101F NC010 Nylon 6-6, Natural Grade	ASTM D3935-21 ISO 11963:2012
	513A Neoprene Rubber	EN 1641:2009 ISO 7405:2018
	Clear PVC	ASTM D3935-21 ISO 11963:2012
	Diamond	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018



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Product Family	Material	Material Compliance Standard
	Tracing Acetate	ASTM D706
	Pro-fax SR549M Polypropylene Copolymer	ASTM D5857
	Anodized MIL-A-8625 Type III Class 2 Aluminum	ASTM F603-12
	Chrome Plating	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018
Headgear	Stainless Steel (302)	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A580/A580M
	Acrylic	ASTM F3087
	Cotton Fabric	ASTM D5867 ASTM D6554
	Natural Latex Rubber	EN 1641:2009 ISO 7405:2018
	Denim Fabric	ASTM D5867 ASTM D6554
Orthodontic Multi-Family Appliances	Silicone Fluid 1000	EN ISO 10993-1:2020

### SECTION 3 : RoHS (EU) 2011/65/EU, (EU) 2017/2012, (EU) 2015/863

The EU's Restriction of Hazardous Substances (RoHS) Directives are related to electrical and electronic equipment and not specifically to plastic and metal raw materials. This product complies with the RoHS Directive 2017/2012, 2011/65/EU and 2015/863 regarding the limits of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE).

### SECTION 4 : California Proposition 65

Per California Proposition 65 List of Carcinogens or Reproductive Toxicants, RMO Orthodontic Accessories do not contain any chemical known to the State of California to cause cancer, birth defects, or other reproductive harm. Immediately remove the orthodontic appliance and instruct the patient to seek medical care in case of an allergic reaction.

### SECTION 5 : Nut and Gluten Ingredients

The RMO Orthodontics Accessories are not formulated with any nut or gluten containing ingredients. The manufacturing site of the products does not manufacture or process nut or gluten containing products.

### SECTION 6 : Phthalates

Based upon the information provided to RMO Orthodontics, the above listed products do not contain phthalates such as DEHP, BBP, DBP and DIBP that are listed in the Candidate List of Substances of Very High Concern of the REACH regulation EU 1907/2006