

# Product datasheet O Clasp / OK Clasp

# **1** Description of the product / intended use / company

Product group: Trade name:	Clasps orthodontics O Clasp / OK Clasp
Intended use:	Manufacture of removable prosthetic, orthodontic and general appliances used in the patient's mouth for the correction of tooth and jaw malocclusions or for prosthetic tooth replacement.
Manufacturer / Supplier:	SCHEU-DENTAL GmbH Am Burgberg 20 58642 Iserlohn Germany Tel. +49 2374 9288-0 gmra@scheu-dental.com

# 2 Composition / information on ingredients

### **Chemical characterization**

Designation:

Stainless steel 1.4301 X5CrNi18-10

### **Components:**

Description	CAS No	Quantity	
Carbon (C)	7440-44-0	≤ 0.07 %	
Silicon (Si)	7440-21-3	≤ 1.00 %	
Manganese (Mn)	7439-96-5	≤ 2.00 %	
Phosphorus (P)	7723-14-0	≤ 0.045 %	
Sulfur (S)	7704-34-9	≤ 0.015 %	
Chromium (Cr)	7440-47-3	= 17.5 – 19.5 %	
Molybdenum (Mo)	7439-98-7		
Nickel (Ni)	7440-02-0	= 8.0 - 10.5 %	
Vanadium (V)	7440-62-2		
Nitrogen (N)	7727-37-9	≤ 0.11 %	
Iron (Fe)	7439-89-6	rest	



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#### 3 Handling and storage

#### Handling

Information for safe handling:

Only to be used for the above-mentioned indication and by qualified specialist personnel.

Contains nickel; allergic reactions in sensitized persons cannot be ruled out

Not suitable for MRI. Parts of orthodontic appliances can break off and be accidentally inhaled or swallowed. The appliance must no longer be worn if it is visibly damaged.

#### Storage

Storage conditions:

No special conditions required

## 4 Physical, chemical, mechanical and biological properties

### 4.1 General properties

Properties	Guideline	Value	
Form	-	solid	
Colour	-	grey odourless	
Odour	-		

### 4.2 Biological properties / Biocompatibility

A biological evaluation was carried out for the material in accordance with DIN EN ISO 10993-1. It meets the requirements regarding biocompatibility for medical devices.

### **5 Stability and reactivity**

#### **Thermal decomposition / Conditions to avoid:** No decomposition by intended use.

## 6 Disposal

The raw material can be recycled after separation or deposed of like commercial or household waste.

The above information is provided to the best of our knowledge. In addition to the information provided, it is recommended to check the suitability of the products individually regarding the respective application and associated procedures and purposes.

Serious incidents in connection with the use of the product shall be reported immediately to the manufacturer (<u>qmra@scheu-dental.com</u>) and the competent authority.

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