

# Safety Data Sheet on the basis of EC 1907/2006

Stand: 2023/08



## SECTION 1: Identification of the products and of the company

### 1.1. Products

Medical Products for dental use

**Mouth mirrors:** SEplus, Economy,  
TOPvision FS Rhodium, TOPvision FS,  
MEGA FS Rhodium, MEGA FS,  
ULTRAvision FS, ULTRA FS  
Laryngeal Mouth Mirrors  
MEGAmicro, ULTRAmicro  
MICROflex rhodium, MICROflex ultra  
BLACKline Mouth Mirrors

**Handles for mouth mirrors:** Handles  
BLACKline Handles

### 1.2. Details of the Manufacturer

E. HAHNENKRATT GmbH  
Benzstr. 19  
DE-75203 Königsbach-Stein  
Phone: +49 7232 3029-0  
E-Mail: info@hahnenkratt.com  
PRRC: Sibylle Schepperheyn (MDR(EU)2017/745: PRRC - Person Responsible for  
Regulatory Compliance)

## SECTION 2: Hazards identification

### 2.1. Warning information

Possible danger to human being and environment is unknown, under the condition that the products are stored and used appropriated as medical products for dental use.

### 2.2. Other hazards

#### 2.2.1. Side effects

Under appropriate treatment and application, unwanted side effects are very rarely to be expected. Immune reactions (such as for example allergies) however cannot be entirely excluded. We kindly ask you to inform us if unwanted side effects become known to you.

#### 2.2.2. Contra-indications / Interactions

In case of hypersensitivity of the patient to one of the components, this medical product is not allowed to be used or just under the strict control of the attending dentist. You get information about the composition of this medical product in the tables. The dentist has to consider, while using this medical product, the known cross-reactions or interactions of the medical product with other medical products or materials, already applied in the mouth.



## SECTION 3: Composition / Information of ingredients

### 3.1. Substances and mixtures

#### 3.1.1. Stainless steel according ISO 21850-1

(Dentistry – Materials for dental instruments – Part 1 Stainless steel)

##### Mouth mirrors:

Composition of Stainless Steel

(1.4301 acc. to EN 10088 / AISI 304):

C	max. 0,07 %
Si	max. 1,00 %
Mn	max. 2,00 %
P	max. 0,045 %
S	max. 0,015 %
Cr	17,50 % - 19,50 %
Ni	8,00 % - 10,5%
N	max. 0,10 %
Remainder:	Fe

##### Mouth mirrors MICROflex:

Composition of Stainless Steel

(1.4404 acc. to EN 10088 / AISI 316L):

C	max. 0,030 %
Si	max. 1,00 %
Mn	max. 2,00 %
P	max. 0,045 %
S	max. 0,015
Cr	16,5 % - 18,5 %
Mo	2,00 – 3,0 %
Ni	10,00 % - 13,0 %
N	max. 0,10 %
Remainder:	Fe

##### Handles for mouth mirrors:

Composition of Stainless Steel

(1.4305 acc. to EN 10088 / AISI 304):

C	max. 0,10 %
Si	max. 1,00 %
Mn	max. 2,00 %
P	max. 0,045 %
S	0,15 % – 0,35 %
Cr	17,00 % - 19,00 %
Ni	8,00 % - 10,00 %
N	max. 0,10 %
Cu	max. 1,00 %
Remainder:	Fe

#### 3.1.2. BLACKline

DLC (Diamond-Like Carbon) coating

#### 3.1.3. Mirror Glass

SEplus, Economy (RS):

TOPvision FS Rhodium, MEGA FS Rhodium:

TOPvision FS, MEGA FS:

ULTRAvision FS, ULTRA FS

Laryngeal Mouth Mirrors:

FS: Front Surface Mirror Coating

RS: Rear Surface Mirror Coating

Float Glass coated with Silver

Float Glass coated with Rhodium

Float Glass coated with Chrome + Titanium

Float Glass coated with Siliciumdioxid + Metall-Oxid

Float Glass coated with Rhodium

#### 3.1.4. Insert: Silicone



## SECTION 4: First aid measures

### 4.1. Description of first aid measures

After inhalation:	not applicable, if necessary seek medical help immediately no steam emission is possible
The contact with skin or mucous membrane:	is usual while intended use
After contact with eye:	not applicable, if necessary seek medical help immediately
After swallowing:	not applicable, otherwise seek medical help immediately
Information for the doctor:	None known

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Water, foam, dry chemical extinguish. Un-appropriated measures are unknown.

### 5.2. Special hazards arising from the substance or mixture

Unknown

## SECTION 6: Accidental release measure

### 6.1. Environmental precautions / Reference to other sections

Collect parts and remove them as described under Section 13: Disposal considerations

## SECTION 7: Handling and Storage

### 7.1. Precautions for safe handling

Information is given in the "EN ISO 17664-1 Manufacturer Information for the processing of medical devices" incl. the Appendixs. The mentioned precaution warnings, the "Product-related warnings" as well as the specific "Inspection and functional check" must be observed.

E.g. mouth mirrors have to be screwed onto handles with the same kind of thread. Please make sure that the mouth mirror is screwed properly to the handle and check the function according to "EN ISO 17664-1 Manufacturer Information".

### 7.2. Conditions for safe storage

In dry condition. Apart from that no special requirements are necessary.

These products are suitable for long term storage between -10° C and +45° C. The products can be sterilized. Thus short term (up to 2 weeks) deviations from the recommended temperatures do not affect significantly the product performance. Transportation by non-temperature controlled means is therefore acceptable, as well as short term temperature deviations during storage.



## SECTION 8: Hygiene Measures

### 8.1. Sterilisation Methods

Product is not supplied sterile. The instruments can be processed by all methods, used usually for mouth mirrors and handles. Please see our "EN ISO 17664-1 Manufacturer Information".

## SECTION 9: Change of Condition

### 9.1. Information on basic physical and chemical properties

Physical State:

Shape	solid
Colour	metallic
Odour	odourless
Change of condition	Melting point: approx. 500° C for glass approx. 1000° C for stainless steel approx. 200° C for silicone insert
Freezing Point	not identified
Density	not identified
pH-Value	not identified
Viscosity	not identified
Water-soluble	insoluble

## SECTION 10: Stability and Reactivity

### 10.1. Decomposition

Thermic decomposition:	See under Section 9: Change of Condition	
Further decomposition:	Stainless steel:	Decomposition is unknown
	Glass:	Decomposition is unknown
	Silicone:	Decomposition is unknown
	Silver mirror layer:	Decomposed by acidic liquids
	Rhodium mirror layer:	Decomposition is unknown
	Chrom/Titanium mirror layer:	Decomposition is unknown
	ULTRA mirror layer:	Decomposition is unknown

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Toxic effects are unknown to us. According to our experiences and according to known information the products don't cause any unhealthy effects under the condition they are used appropriated.

The Biocompatibility has been proved as part of the MDR technical documentation.

## SECTION 12: Ecological information

### 12.1. Adverse effects

No harmful impact on environment is known.

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## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

Remove in accordance with the public regulations.

## **SECTION 14: Transport information**

### **14.1. Special precautions**

No dangerous material.  
No special requirements with respect to transportation regulations.

## **SECTION 15: Regulatory information**

### **15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture**

Medical devices according to MDR (EU) 2017/745

## **SECTION 16: Other information**

### **16.1. Statement**

The above mentioned information are based on our latest knowledge and assures no technical features. Existing laws and regulations must be observed by all receivers and users under their own responsibility. According to the MDR (EU) 2017/745, medical devices may only be used by the dentist himself or by instructed, special qualified staff.