

# MATERIAL SAFETY DATA SHEET

#### **BonaFit Reamer**

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### 1. Product: BonaFit Reamer Endodontic drills.

### 2. Material:

Stainless steel according ISO 7153 -1 (surgical instruments - metallic materials).

#### **Composition:**

C 0,43 - 0,50 % Si max 1,00 % Cr 12,50 - 14,50 Balance: Fe

Mn max 1,00 %

P max 0.045 %

S max 0,030 %

# 3. Warning information:

Possible danger to human being and environment are none known, provided appropriate storage and handling. Material is according ISO 7153 - 1 (surgical instruments - metallic materials).

## Hygiene measures and sterilisation methods:

Sterilisation by autoclave or hot air before initial use.

### 4. First-aid measurements:

Usual appropriate measurements.

### **5.** Measures for fire extinction:

Fire can be extinguished by usual appropriate means.

# **6. Measures in case of unintentional destruction:** No special requirements.

7. Storage: In original packaging (plastic bag or box), in dry condition.

### 8. Exposure and personal protection:

Up to now, concerning this product no unwanted side effects became known to us.

Unwanted side effects are very rarely to be expected by appropriate treatment and application. However in general immune reactions (such as for example allergies) can be never entirely excluded.

In case of hypersensitivity of the patient to one of the components, this medical product is to be used under the latitude and the medical supervision of the attending dentist. 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.

### 9. Physical and chemical properties:

Condition: solid Odour: none Ph value: not applicable
Colour: metallic Viscosity: not applicable Water - soluble: insoluble

## 10. Stability and reactivity:

Dangerous reactions are unknown. Stable and not reactive under appropriate storage.

### 11. Information on toxicology:

Material according ISO 7153-1 (surgical instruments-metallic materials). Cytotoxic effects are unknown.

# 12. Information on ecology: Damaging effects are unknown.

### 13. Information about disposal:

Can be removed together with common trash inline with public regulations.

### 14. Transport information:

No special requirements with respect to transport regulations.

### 15. Regulations:

Drills are a class IIa Medical Devices according to Directive EEC 93/42.

### 16. **Others:**

The above mentioned information are based on our latest knowledge and describes the product as for safety aspects without assuring technical properties and features.

Existing law and regulations must be observed by the user its own responsibility.

According to the European Directive EEC 93/42, these Medical Devices may only be used by the dentist himself or by instructed, special qualified staff.

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