1: Identification of the device

1.1. Product identifier

Diamond bur for the dentist
GMDN code: 16670
UMDNS code: 16-670

1.2. Relevant identified uses of the device and uses advised against

Intended use:
Diamond burs are intended for multiple use during dental treatments.
They are used for reduction, excavation and cutting or for surface conditioning of dental tissues such as bone, dentin and dental enamel and dental materials such as composites, metal alloys, ceramics and dental resins.
They are intended for use by trained technicians and dentists.
They are powered by a handpiece or right angle attachment.
Note: There are handpiece and right angle attachments drives with collets for handpiece, right angle shank and friction grip (FG) shanks. These must comply with the relevant ISO standards
Contraindications:
Diamond burs shall not be used, if:

1. The instrument is not cleaned and disinfected/sterilized according to instructions for use before treatment.
2. Sufficient cooling cannot be provided.
3. The health status of the patient can be affected negatively by accompanying medication or stress cause by the treatment.
4. The mental health of the patient can be affected negatively by the noises or stimuli caused by the treatment. (e.g. states of fear)
5. The abrasion/dust caused by the use of the burs on restauration materials is allergenic or toxic and can be swallowed or inhaled by the patient or dentist.

1.3. Details of the supplier of the safety data sheet

Hopf, Ringleb & Co. GmbH & Cie. , Gardeschützenweg 82, 12203 Berlin – Germany
Trade name: HORICO®
Phone: +49 30 830 003 – 0
E-Mail: horico@horico.de

2: Hazards identification

2.1. Classification of the device

medical devices of risk class 2a (active device, non steril) according to European regulations, Class 1 according to FDA regulations and class 2 according to Canadian regulations)
According to RKI directives regarding reprocessing of medical devices diamond burs are semi-critical B.
Device needs to be disinfected or sterilized before first and before every further use according to reprocessing instructions provided by the manufacturer.

2.2. Identification and Symbols

Primary code: follows HIBC-Standard: beginning with licensed manufacturer code (HIBCC)
+EHOR<Item number><Packing index>/<Lot number>/<Manufacturing date>
If item is medical device it is listed in the UDI Databases of EUDAMED (EU) and GUIDID (FDA USA)

Symbols used on the label:

	manufacturing date
	address of manufacturer
	Consult instructions for use
	To be sterilized in the autoclave

$\circlearrowleft_{empf.}$	Recommended turning speed for best results
$\circlearrowleft_{max}$	Maximum turning speed, which must not be exceeded
MD	Medical device
CE 0297	Approved quality management system according to directive 93/42/EEC with ID of notified body

2.3. Other hazards

Nickel can cause allergic reactions, occurrence if used as intended: very rare, no case reported
Use only drives which are in good technical and hygienic condition.

3: Composition/information on componants

Stainless steel blank, galvanically coated with a nickel bonding, holding diamond grid as abrasive.

4: First aid measures

4.1. Description of first aid measures

Intended use can cause small lesions on gingiva of the patient.
Disinfection of the lesion if applicable is recommended. The general health condition of the patient need to be considered.

4.2. Most important symptoms and effects, both acute and delayed

Light bleeding, inflammation of the lesion

4.3. Indication of any immediate medical attention and special treatment needed

Non under normal conditions

5: Firefighting measures

5.1. Extinguishing media

No restrictions

5.2. Special hazards arising from the device

Non

5.3. Advice for firefighters

Non

6: Accidental release measure

The device itself carries no hazards, but infectious tissues and allergenic res. toxic material (depending on the restauration material) can be spread while working with the bur and afterwards.

6.1. Personal precautions, protective equipment and emergency procedures

Accelerator for the bur (Air turbine or micro motor) must be in faultless condition.
Personal infection protection is recommended (surgical mask, eye protection and gloves)

6.2. Environmental precautions

Chair and other surfaces of the practice need to be disinfected after each patient treatment

6.3. Methods and material for containment and cleaning up

Storage after use and before reprocessing according to infection control protocol of the practice.

7: Handling and storage

7.1. Precautions for safe handling

Points of some types of burs can be sharp – surgical gloves

7.2. Conditions for safe storage, including any incompatibilities

Before use and after reprocessing: Dry and clean storage
Shelf life is only limited by the durability of the packing

7.3. Specific end use(s)
Prior to use, ensure that:
1. Users and assistance where mouth protection, goggles and gloves and that the environment (treatment unit, etc.) is appropriately disinfected, because infection particles can be scattered by the fast rotation and spray water.
2. Use only drives which are in good technical and hygienic condition. Please follow the operating instructions of the handpiece manufacturer!
Please note explicitly that most preprocessing units generally do not lubricate the collet and bearings. But handpiece manufacturers usually require this after 20 to 30 minutes of operation.
3. Please clamp the shaft of the instrument as deeply as possible. If instruments are loose or protrude too far, they can fly off, bend or break, causing injuries, or be swallowed or aspirated.
4. Select the speed such that the maximum allowed RPM is not exceeded (see the table for maximum speed). Exceeding the maximum speed increases safety risks, reduces the quality of work and generates heat. The recommended speed, which is generally about half the maximum speed, produces the best work results and reduces undesirable secondary effects to a minimum.
5. Ensure sufficient air/water cooling (minimum 60 ml/min).
6. Processing extraneous materials in the mouth, such as filling materials, can release nanoparticles of these. Depending on the starting material, these may be bioactive. Thus suction and possibly other protective measures such as a dental rubber dam, etc. are recommended.
7. Please bring the instrument up to working speed outside of the mouth or prior to contact with the workpiece. If vibrations occur, the instrument is bent and can no longer be used!
8. Please work with as little pressure as possible (about 50 g, corresponding to the pressure applied when writing) and do not twist the instrument. Higher pressure only leads to greater heat development, faster wear and inferior work results.
9. If the instrument jams, stop the handpiece, carefully remove the instrument without twisting it and check for damage before using it again.
10. Dull and damaged instruments must no longer be used. Please check the instruments prior to each use. Signs of damage with diamond instruments are blank spots on the working part, bent instruments which produce vibrations when starting and changes in the original form. Carbide instruments exhibit damaged and deformed cutting edges or breaks.
11. Long instruments are not suited for canals with curvature: there is a risk of breakage.

If the safety instructions are not followed, damage can occur to the tooth and surrounding tissue or the workpiece, possibly endangering the user, the patient and other persons.

8: Exposure controls/personal protection
Non

9: Physical and chemical properties
9.1. Information on basic physical and chemical properties
Stainless steel:
Physical state at 20°C and 101,3 kPa: solid
Melting point: about 1375°C
Boiling point: about 2750°C
Relative density: 7,9g/cm³ at 25°C
Surface tension: n.a.
Water solubility: n.a.
Burning point: n.a.
Inflammability: not inflammable
Explosion characteristics: not explosive
Self-ignition: no self-ignition
Oxidative characteristics: not oxidative
Stability in organic solvents: n.a.

Nickel layer (galvanically applied, solid):

Physical state at 20°C and 101,3 kPa: solid
Melting point: 1455°C
Boiling point: 2730°C
Relative density: 8,9g/cm³ at 25°C
Surface tension: n.a.
Water solubility: n.a.
Burning point: n.a.
Inflammability: not inflammable
Explosion characteristics: not explosive
Self-ignition: no self-ignition
Oxidative characteristics: not oxidative
Stability in organic solvents: n.a.

Diamond grit:
Physical state at 20°C and 101,3 kPa: solid
Melting point: above 600°C
Boiling point: 2730°C
Relative density: ca. 3,5g/cm³ at 25°C
Surface tension: n.a.
Water solubility: n.a.
Burning point: n.a.
Inflammability: not inflammable
Explosion characteristics: not explosive
Self-ignition: no self-ignition
Oxidative characteristics: not oxidative
Stability in organic solvents: n.a.

9.2. Other information
Non

10: Stability and reactivity
10.1. Reactivity
Stable under normal conditions
10.2. Chemical stability
Stable under normal conditions
10.3. Possibility of hazardous reactions
Stable under normal conditions
10.4. Conditions to avoid
non
10.5. Incompatible materials
Strong acids and oxidants
10.6. Hazardous decomposition products
Nickeltetracarbonyl gas under deoxidizing atmosphere

11: Toxicological information
Oral: non toxic
Inhalation: n.a.
Dermal: n.a.
Eyes: mechanical irritation

Sensibilization:
Repiratory system: no information available
Skin: no information available – nickel can cause allergic reaction in case of longer expositions

12: Ecological information
12.1. Toxicity
Non

12.2. Persistence and degradability
n.a.

12.3. Bioaccumulative potential
Non, as nickel is solid

12.4. Mobility in soil
Non, as nickel is solid

12.5. Results of PBT and vPvB assessment
Not classified as PBT and vPvB

12.6. Other adverse effects
Non identified

13: Disposal considerations

13.1. Waste treatment methods after use
Disposal according to local and national regulations for potentially infectious material

13.2. Waste treatment methods before use
Disposal according to local and national regulations for recycling of metals

14: Transport information

14.1. UN number
Non

14.2. UN proper shipping name
non

14.3. Transport hazard class(es)
Non

14.4. Packing group
Non

14.5. Environmental hazards
Non

14.6. Special precautions for user
Non

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
n.a.

15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the device
ISO 13485:2016; Directive 93/42/EEC; MDR of EU, USA and Canada
ISO 7711-1:2009 - Dental rotary instruments - Diamond instruments - Part 1: Dimensions, requirements, marking and packaging

15.2. Chemical safety assessment
N.a.

16: Other information
non