



Device Description

Product Name: **Dental Air Polishing Handpiece**

Model No.: **AP-H、AP-H Plus、AP-Mini、AP-Mini+**

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Product name 产品名称

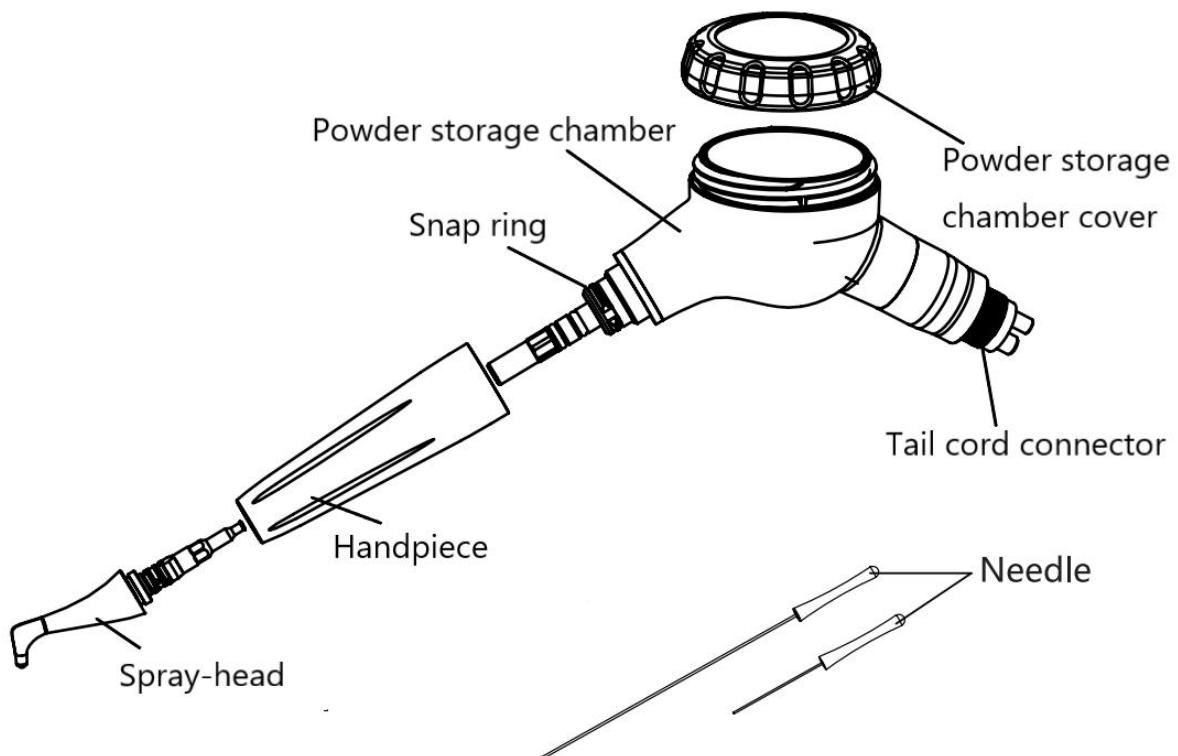
Name: Dental Air Polishing Handpiece

Model: AP-H、AP-H Plus、AP-Mini、AP-Mini+

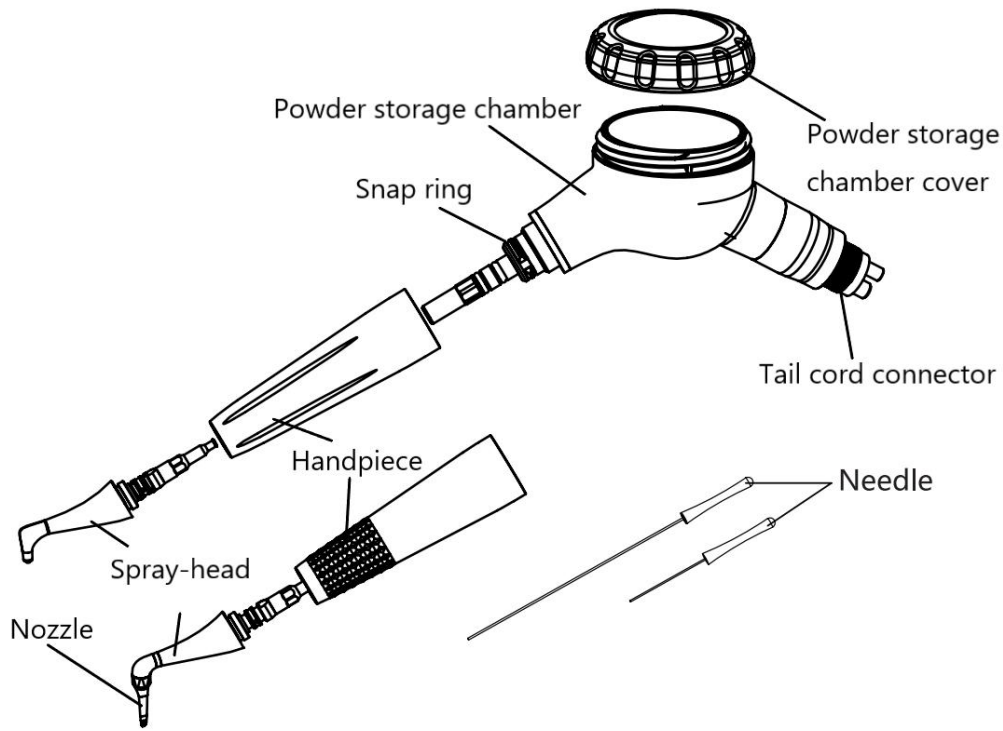
Device Composition 设备组成

AP-H、AP-Mini: This product is composed of AP-1 Plus handpiece, powder storage chamber, tail cord connector and needle.

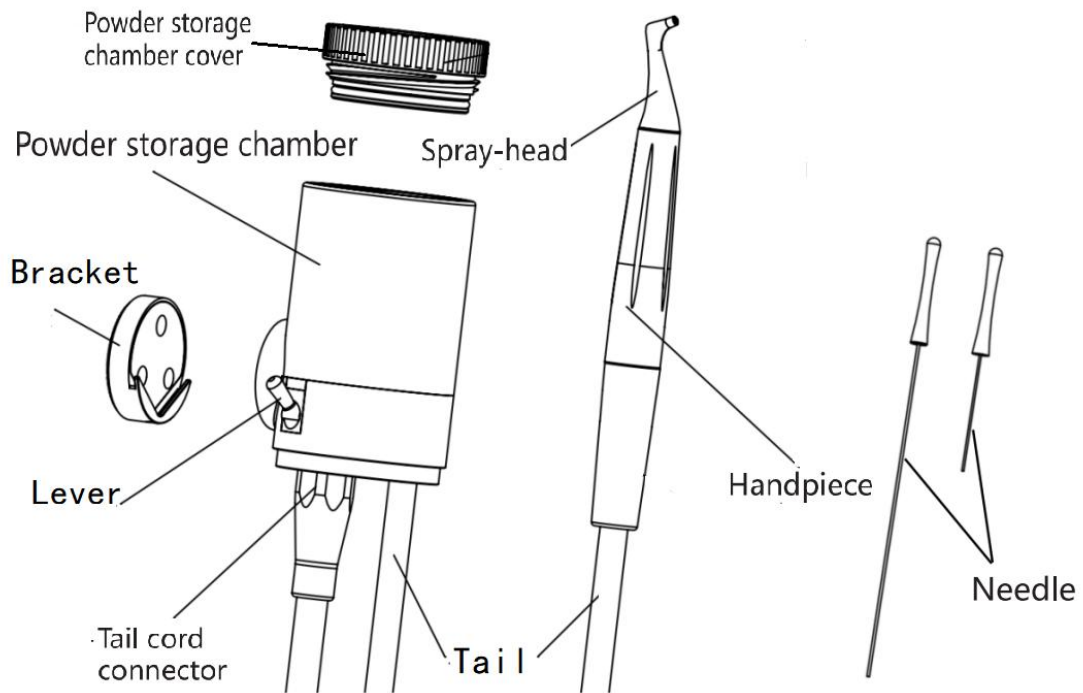
AP-H Plus、AP-Mini+: This product is composed of AP-1 Plus handpiece, AP-2 Plus handpiece, nozzle, powder storage chamber, tail cord connector and needle.



AP-H



AP-H Plus



AP-Mini

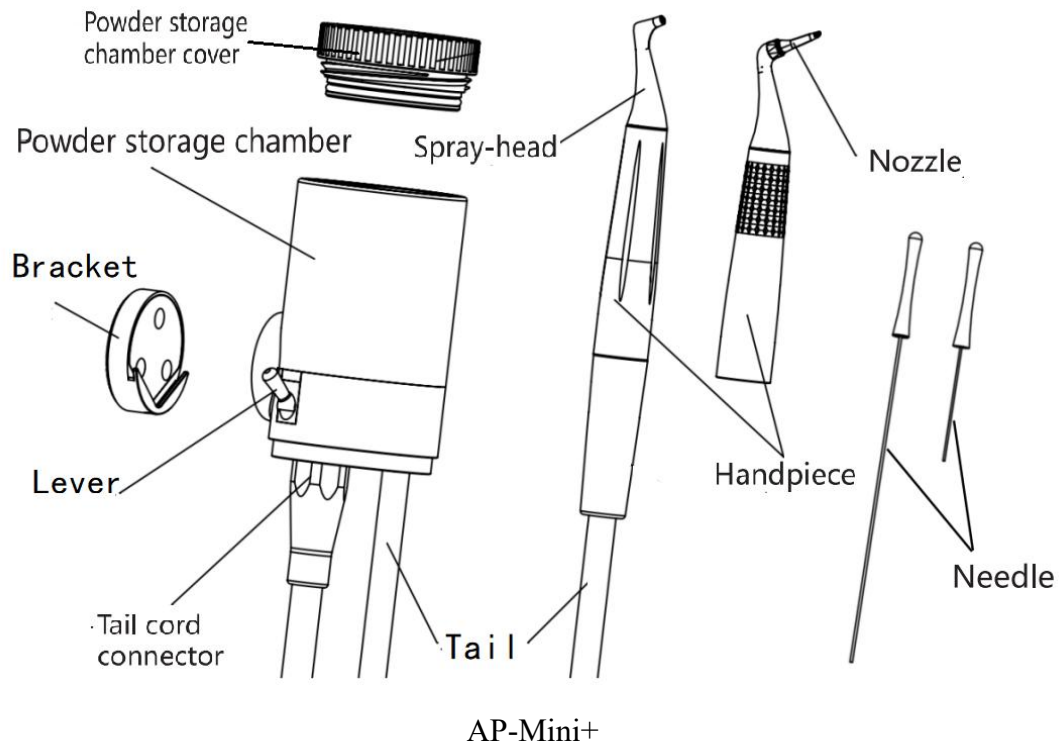






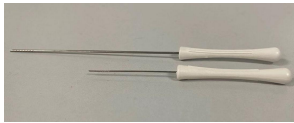


Figure 1-1 Structure of Dental Air Polishing Handpiece

The details of each component given in the table 1-1 表1-1中给出了每个组件的详细信息

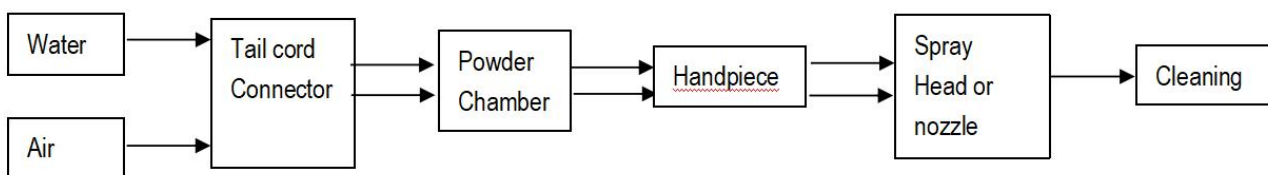
Table 1-1 Description of components of Dental Air Polishing Handpiece						
Number	Accessories	Fig	Configuration	Description	Function	Remark
1	Handpiece		AP-1 Plus	Compatible with powder storage chamber of AP-H Plus and AP-H; Compatible with tail of AP-Mini and	For supragingival use. Applied part, to transfer water and powder	Key functional component

				AP-Mini+		
2	Handpiece		AP-2 Plus	Compatible with powder storage chamber of AP-H Plus; Compatible with tail of AP-Mini+	For subgingival use. Applied part, to transfer water and powder	Key functional component
3	Powder storage chamber		AP-H, AP-H Plus	The front end is connected to the handle, and the rear end is connected to the tail wire of the dental chair	Used to hold sand powder and transfer water and powder	Key functional component
4	Powder storage chamber		AP-Mini, AP-Mini+	Used to hold sand powder and transfer water and powder	Used to hold sand powder and transfer water and powder	Key functional component
5	Tail		AP-Mini, AP-Mini+	Connect the Powder storage chamber and	Used to transfer water and air	Key functional component

				tail of AP-Mini and AP-Mini+		
6	Nozzle		SUB-A	Applied part for AP-H Plus and AP-Mini+	For subgingival use. To transfer water and powder	Key functional componen t
7	Needle		/	Maintenance tools	To Clean the residual powder in the handpiece tube	Real accessory

Operation Principle 工作原理

The Dental Air Polishing Handpiece is an air-driven handpiece which will be supplied with water and air through the pipe and the coupling of a dental treatment unit. The device contains air and water pipes inside which supply air for driving the turbine assembly rotating and cooling water for work site as well as supply air and water for creating spray. The tail cord connector is connected to the dental treatment unit. The compressed air provided by the dental treatment unit drives the dental sandblasting powder in the powder chamber, and is sprayed with water through the handpiece and nozzle to the tooth surface, remove plaque and pigment on the tooth surface, and realize the cleaning.



Intended Use, User and Patient 预期用途、用户和患者

Intended use 预期用途

The AP-H Plus and AP-Mini+ can be used for removal of supragingival and subgingival biofilm and pigment and for implant maintenance.

The AP-H Plus and AP-Mini+ can be used for removal of supragingival biofilm and pigment.

Intended user: Dentist, Dental hygienis 面向的用户:专业牙医, 牙科保健师

Intended patient: Patients who need removal of supragingival and subgingival biofilm and pigment and for implant maintenance.

Contraindication and Precautions 禁忌症和注意事项

Contraindication 禁忌症

- 1) Patients with endocardial inflammation;
- 2) Patients pregnant or lactating;
- 3) Patients with a contagious illness or disease;
- 4) Patients with an immune deficiency disease (neutropenia, granulocytopenia, agranulocytosis, diabetes, hemophilia);
- 5) Patients under irradiation treatment, chemotherapy, or administration of an antibiotic.

Precautions 注意事项

When using the equipment, take the following precautions. Otherwise, problems may occur and the equipment may not function correctly.

使用设备时, 请注意以下事项。否则, 可能会发生问题, 并且设备可能无法正常运行。

- 1) Excessive air pressure will cause cracks or ruptures on the powder storage chamber and powder storage chamber cover of the Dental Air Polisher, and even cause harm to the human body.

过高的气压会导致喷砂枪粉腔和粉腔盖产生裂缝或破裂, 甚至导致人体伤害。

- 2) Fully dry the Dental Air Polisher interface and the handpiece pipeline interface before connection, so as to avoid the spray-head blockage from damp powder during use.

连接之前充分干燥喷砂枪接口和手机管线接口, 以免使用时砂粉受潮导致喷头堵塞。

- 3) Only woodpecker brand powder can be used, and the amount of the powder added should not exceed the maximum scale mark.

仅可使用啄木鸟品牌牙科喷砂粉, 加砂量切勿超过最大刻度线。

- 4) It is forbidden to pull out the tail plug when the handpiece is working.

注意手柄在工作状态下禁止拔出尾插;

- 5) Only subgingival powder can be used for subgingival air polishing.

龈下喷砂仅可使用龈下喷砂粉。

Specification 规格

Product specifications 产品规格

Model: AP-H、AP-H Plus

Size: 177mm×52mm×88mm

Model: AP-Mini、AP-Mini+

Size: ϕ 50mm×95mm

Main technical parameters

Input water pressure:

1bar to 2bar (0.1-0.2MPa)

Input air pressure:

3bar to 4bar (0.3-0.4MPa)

Operation mode: continuous operation

Weight:

AP-H、AP-H Plus: About 0.150kg

AP-Mini、AP-Mini+: About 0.250kg

Connector: Meet the requirements of ISO 9168:2009

Operation environment 使用环境

Ambient temperature: + 0°C ~ +40°C

Relative humidity: 30% ~ 75%

Atmospheric pressure: 50kPa ~ 106kPa

Performance 性能

Item	Detailed information
Noise	\leq 80DB
Air Flow Volume(4.5bar \geq input Air pressure \geq 2.5bar)	\cong 40NL/min
water Flow Volume (Input water pressure \geq 1.5bar)	\cong 40ml/min (\pm 50%)

Hygienic protection 卫生防护

Pretreatment of Handpiece and Powder Storage Chamber

(1) Disassembly

AP-1 Plus: Loosen the nozzle counterclockwise;

AP-2 Plus: Loosen the nozzle counterclockwise.

(2) Cleaning

1) Cleaning the handpiece and spray-head

Tools: Air gun, soft cloth for cleaning and drying, brush.

- Remove any externally attached soiling by brushing carefully with a soft surface brush or cloth.
- Soak the handpieces and spray-heads in the cleaning solution for, as a minimum, the time and the concentration specified by the manufacturer of the cleaning agent (ENZOL, 2 %, 10 min).
- Brush all lumens and surfaces with a suitable lumen / surface brush until all visible soiling is removed.
- Rinse through all product lumina (e.g. irrigation and aspiration connection) with the cleaning solution (ENZOL, 2 %), at least 5 times in the flow direction (no back rinsing), using a disposable syringe (min. volume 50 ml)
- Submerge all components completely in deionized water.
- Rinse through all product lumina (e.g. irrigation and aspiration connection) with deionized water at least 3 times in the flow direction (no back rinsing), using a disposable syringe (min. volume 50 ml) .
- Repeat the cleaning process if the last rinse does not run clear, or if stains are still visible on the product.
- Use a dry absorbent soft cloth to wipe off the residual water on the handpiece and spray-head.

2) Cleaning the chamber

- Clean the outer surface of the chamber and the chamber cover, the threads of the chamber and cord connector using a cleaning wipe with proven efficacy (Enzol 2%) at least 5 times, until there are no visible stains.
- Then wet the clean soft cloth with purified water or distilled water, wipe the outer surface of the chamber and the chamber cover, the threads of the chamber and cord connector thoroughly for 5 times, to remove the residual cleaning agent on the surface.
- Use a dry absorbent soft cloth to wipe off the residual water on all components.

[Note]:

- a. The use of scouring powder or an abrasive sponge will damage its surface.

b. Do not submerge the chamber in a cleaning solution bath. It would be likely to be damaged.

(3) Disinfection

- Disinfect the outer surface of the chamber and the chamber cover, the threads of the chamber and cord connector using 70% isopropyl alcohol or other EPA recognized surface disinfectant, following carefully the instructions provided by the disinfection solution manufacturer.
- Then wet the clean soft cloth with sterile water, wipe the outer surface of the chamber and the chamber cover, the threads of the chamber and cord connector thoroughly for 5 times, to remove the residual disinfectant on the surface.
- Use a dry water absorbent sterile cloth to wipe off the residual water on all components.

[Note]:

- a. Make sure the handpiece connection of the cord is dry.
- b. Do not sterilize the chamber and cord. It would be likely to be damaged.

(4) Drying

If the automatic drying function is not included in your cleaning and disinfection process, please perform drying after cleaning and disinfection.

- 1) Dry all components with a dry absorbent soft cloth.
- 2) Lay a clean white cloth on the workbench, align the handpiece and spray-head with the cloth, and then blow the handpiece and spray-head with filtered dry compressed air (maximum pressure of 3 bar) for drying. If there is no liquid sprayed on the white cloth, the drying is completed.

[Note]:

- a. Product drying must be done in a clean place.
- b. The equipment in use should be inspected and maintained regularly.
- c. The chamber cover must be absolutely dry before closing.

(5) Packaging

Place the handpieces and spray-heads respectively in a sterilization bag or pouch cleared by FDA.

[Note]:

- a. The accessories should be bagged in a sterilization pouch that is validated for use in a 132°C pre-vacuum steam sterilization cycle.
- b. The sterilization pouch should be sealed according to the manufacturer's instructions.

(6) Sterilization

Only the handpieces and spray-heads can be sterilized. We recommend sterilization in a fractional pre-vacuum cycle at 132°C for 4 min and a drying time of minimum 20 min.

Pretreatment of nozzle

Immerse the nozzle in the cleaning solution for at least the time and concentration specified by the cleaning agent manufacturer (enzol, 2%, 10min).

Storage 储存

The product should be handled with care and away from the earthquake source. Ensure that it is installed or stored in a cool, dry and ventilated place indoors.

Do not mix the product with toxic, corrosive, flammable, or explosive materials during storage.

The product should be stored in the environment with relative humidity of 10% ~ 90%, atmospheric pressure of 50kPa ~ 106kPa and temperature of -10°C ~ +40°C .

After sterilization, the product should be packaged in a medical27 sterilization package or a clean sealed container and stored in a special storage cabinet. The storage time shall not exceed 7 days. If exceeded, it should be reprocessed before use.

● Precautions 注意事项

The storage environment should be clean and be disinfected regularly;

Product storage must be batched, marked and recorded

Transportation 运输

Avoid excessive impact and vibration during transportation. Handle it with care and avoid inversion.

It should not be mixed with dangerous goods during transportation.

Avoid sunlight, rain or snow during transportation.

Lifetime 使用期限

The system lifetime is 5 years.

Reference to previous and similar generations of the device 参考上一代和类似的设备

The AP-H/AP-H Plus/AP-Mini/AP-Mini+ Dental Air Polishing Handpiece are designed and manufactured by Guilin Woodpecker Medical Instrument Co., Ltd., the device is reference to

similar device such as NSK Perio-Mate, EMS AIR-FLOW handy 3.0 device for dental prophylaxis to design, and this is the first time to apply for CE mark under MDR, hence, there is no information reference to previous and similar generations of the device.

Statement 声明

Guilin Woodpecker Medical Instrument is not use of and will not use of the following materials to manufacture the electric motor:

- derivatives of tissues or cells of human origin;
- derivatives of tissues of cells of animal origin;
- medicinal substances;
- substances or combination of substances that are absorbed or locally dispersed into the human body;
- presence of CMR and/or endocrine-disrupting substances, including phthalates;
- Nanomaterials;
- Latex.

Package and size 包装及尺寸

Please refer to Sample of Label and Language Information for details.
(ZMN-YF-AV5-01-001-002-2).

Main Raw Materials List 主要原材料清单

产品/部件名 Product / part name	Material 材料
手柄 Handpieces	手柄的材料是阳极氧化铝和不锈钢，阳极氧化铝的牌号是6061，不锈钢的牌号为303F、304和316;The material of the handpiece is anodized aluminum and stainless steel, the grade of anodized aluminum is 6061, and the grades of stainless steel are 303F, 304 and 316.
喷嘴 Nozzle	喷嘴的材料为 PE。 The material of the nozzle is Polyethylene (PE).

Disposal 处置

When disposing of this equipment, or any of its components (such as fuses), follow all applicable national and local laws and guidelines.

处置此设备或其任何组件（例如保险丝）时，请遵循所有适用的国家和地方法律和准则。

GMDN Code

Code: 45406

A hand-held, dental device that is a component of a dental abrasive air jet system and which is used to direct a concentrated jet of air combined with an abrasive powder, together with water for cooling, to the surface of the patient's tooth or teeth. This device is connected to the control unit that regulates the sources of pressurized air and temperate water. The abrasive, typically in the form of a powder that, depending upon the design of the delivery method, can be contained within a receptacle in this device or a receptacle within the control unit, is mixed with the air and water as this passes through. This is a reusable device.

一种手持式牙科设备，是牙科用磨料喷射系统的组成部分，用于将与磨料粉末结合的空气与冷却水一起集中喷射道患者的牙齿表面。该装置与控制单元相连，控制单元调节压缩空气和温带水的来源。研磨剂通常以粉末的形式存在，根据输送方法的设计，研磨剂可装在本设备的容器或单元的容器中，当研磨剂通过时与空气和水混合，这是一个可重复使用的设备。

Classification 分类

According to the provisions of Rule 6 of Annex 9 of MDR2017/745 : All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or

exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

This product is used to deliver water and powder to the surface of the teeth or gums. It is a short-term, non-invasive device that does not contact with the human heart or central system. When an operator or device misuses energy management or energy exchange methods in a malfunctioning state, consequential damage to oral tissue can occur. Because its application site is only in the oral cavity, it is a low-risk device.

Based on the above analysis, the Dental Air Polishing Handpiece is classified as class IIa.

按照 MDR2017/745 附录八规则 9 的规定：用于注入或交换能量的所有有源治疗器械均归类 IIa 类，除非它们向/从人体注入/吸收能量或与人体交换能量的同时可能会造成危害，并考虑到能量应用的密度和部位，此类器械应归类 IIb 类。

本产品用于传输水和粉末到牙齿或牙龈表面。它是一种短期使用的非侵入性设备，不接触人体的心脏或中枢系统。当操作人员或设备在故障状态下误用能量管理或能量交换方式时，可能对口腔组织造成间接伤害。因为它的应用场所只在口腔，所以属于低风险设备。

综上所述，牙科喷砂枪属于 IIa 类。

Conformity assessment procedure 合格评定程序

Annex IX, (EU) 2017/745, MDR (欧盟) 2017/745, MDR 附件 9

EU Representative 欧盟代表**Name:** MedNet EC-Rep GmbH**Add:** Borkstrasse 10 ,48163 Muenster ,Germany

名称: MedNet EC-Rep GmbH

地址: 德国博斯特大街10号48163曼斯特