

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：浙杭食药监械出 20250960 号
Certificate NO.: 浙杭食药监械出 20250960 号

产品名称：正畸颊面管等产品，见附件（共 4 页）
Product(s): orthodontic buccal tubes, etc. See Attachment (4 Pages)

规格型号：见附件（共 4 页）
Model: See Attachment (4 Pages)

产品注册或备案凭证号：见附件（共 4 页）
Registration certificate(s): See Attachment (4 Pages)

生产企业：杭州星辰三比齿科器材有限公司
Manufacturer: Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.

生产企业住所：浙江省杭州市富阳区春江街道过庭街 619 号
Address of manufacturer: No. 619, Guoting Street, Chunjiang Subdistrict, FuYang District, 311421, Hangzhou, China

生产许可或备案凭证号：浙药监械生产许 20100313 号/浙杭药监械生产备 20180013 号
Manufacturing License(s): 浙药监械生产许 20100313 号/浙杭药监械生产备 20180013 号

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制，出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country (region).

证明有效日期至：2026 年 07 月 08 日
This certification valid until: 2026-07-08

备注：/
Remark: /

Zhejiang Medical Products Administration

(浙江省药品监督管理局)

2025 年 11 月 09 日

医疗器械出口销售证明

(出具单位盖章)

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序号 SN	产品名称 Product(s)	规格型号 Model	产品注册或备案凭证号 Registration certificate(s)
1	正畸颊面管 Orthodontic Buccal Tubes	方丝弓颊面管、直丝弓颊面管、滑动颊面管、圆丝弓颊面管 Edgewise Buccal Tubes, Roth Buccal Tubes, MBT Buccal Tubes, Begg Buccal Tubes	浙械注准 20182170080
2	正畸带环 Orthodontic Bands	光面带环、方丝弓带环、直丝弓带环、滑动带环、圆丝弓带环 Plain Bands, Edgewise Bands, Roth Bands, MBT Bands, Begg Bands	浙械注准 20182170078
3	舌侧扣 Lingual Buttons	IA04-051, IA04-059, IA04-151, IA04-081, IA04-601, IA04-603, IA04-081M, IA04-084M, IA04-311, IA04-312, IA04-361, IA04-362, IA04-306, IA04-305, IA04-303, IA04-314, IA04-083M, IA04-082M, IA04-604, IA10-051, IA10-151, IA17-001, IA17-002, IA17-201, IA17-202, IA17-301, IA17-302, IA17-101, IA17-102, IA04-001, IA04-101, IA10-001S, IA10-001, IA10-001L	浙械注准 20182170077
4	正畸丝 Orthodontic Archwires	镍钛丝、不锈钢丝 NITI Archwires, Stainless Steel Archwires	浙械注准 20182170079
5	游离牵引钩 Sliding Hooks	短型、长型、单钩型、复合钩型、十字型、停止圈 Short Crimpable Hooks, Long Crimpable Hooks, Long Curved Crimpable Hooks, Spiral Crimpable Hooks, Cross Tubes, Crimpable Stops	浙械注准 20182170075

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共 4 页 第 2 页)
 (Page 2 of 4 Pages)

6	正畸托槽 Orthodontic Brackets	方丝弓托槽、直丝弓托槽、滑动托槽 Edgewise Brackets, Roth Brackets, MBT Brackets	浙械注准 20182170076
7	颌前方牵引口外装置 Face Masks	双杆式（可调式、全调式）、单杆式 Face Masks (Adjustable, Universal Adjustable), Adaptable Class and Masks	浙械注准 20162170344
8	陶瓷托槽 Ceramic Brackets	型号：方丝弓托槽、直丝弓托槽、滑动托槽 规格：自锁型（0.022”，0.018”）和结扎型（0.022”，0.018”） Model: Edgewise Brackets, Roth Brackets, MBT Brackets Specifications: Self-Ligating (0.022”, 0.018”), Ligating (0.022”, 0.018”)	浙械注准 20162170821
9	螺旋扩弓器 Expansion Screws	I型、II型、III型 Type I, Type II, Type III	浙械注准 20162170882
10	正畸粘接剂 Orthodontic Adhesive	LA01-101, LA01-102, LA01-103, LA01-104, LA02-101, LA02-102, LA02-103, LA02-104, LA11-101, LA12-101	浙械注准 20212170540
11	方丝弓成型器 Arch Turret	无转矩、带转矩 No Torque, With Torque	浙杭械备 20180066 号
12	牙科用镊 Dental tweezer	型号：托槽镊（规格：前牙无定位片、前牙带定位片、后牙无定位片、后牙带定位片）、颊面管镊 Model: Bracket tweezer (Specifications: anterior without positioning tip, anterior with positioning tip, posterior without positioning tip, posterior with positioning tip), Buccal tube tweezer	浙杭械备 20190054 号
13	正畸托槽定位器 Orthodontic Bracket Positioning Gauge	型号：星形（规格：前牙、后牙）、杆式（规格：单杆双头、前牙活动双头、后牙活动双头）	浙杭械备 20190105 号

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共 4 页 第 3 页)
(Page 3 of 4 Pages)

		Model: Boone Gauge (Specifications: anterior, posterior), shaft model (Specifications: double-ended, anterior double ended, posterior double-ended)	
14	正畸自锁托槽开启器 Instrument for Orthodontic Self-Ligating Bracket	I型、II型、III型、IV型、V型、VI型、VII型、VIII型 Type I, Type II, Type III, Type IV, Type V, Type VI, Type VII, Type VIII	浙杭械备 20190949 号
15	口角拉钩 Cheek and Lip Retractors	型号：U 型，规格：小号、中号、大号； 型号：O 型，规格：小号、大号； 型号：T1 型，小号、大号； 型号：T2 型，小号、大号； 型号：T3 型，小号、大号； 型号：I 型，小号、大号； 型号：Y1 型；Y2 型 Model: U model, Specifications: small, Medium, Large; Model: O model, Specifications: small, Large; Model: T1 model, Specifications: small, Large; Model: T2 model, Specifications: small, Large; Model: T3 model, Specifications: small, Large; Model: I model, Specifications: small, Large; Model: Y1 model, Y2 model.	浙杭械备 20180065 号
16	种植体螺丝起 Orthodontic Positioning Guide	HI50-161; HI50-162; HI50-141; HI50-142; HI50-100; HI50-061; HI50-062; HI50-041; HI50-042	浙杭械备 20230511
17	正畸钳 Orthodontic Plier	HI07-01, HI07-018, HI08-01, HI08-018, HI09-01, HI09-018, HI12-01, HI12-018,	浙杭械备 20180064 号

附件

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证书编号：浙杭食药监械出 20250960 号

(共 4 页 第 4 页)

Certificate NO.：浙杭食药监械出 20250960 号

(Page 4 of 4 Pages)

		I10-01, HI10-018, HI11-01, HI11-018, HI17-01, HI17-018, HI18-01, HI18-018, HI13-01, HI13-018, HI24-01, HI24-018, HI22-01, HI22-018, HI14-01, HI14-018, HI30-01, HI30-018, HI27-01, HI27-018, HI29-01, HI29-018, HI26-01, HI26-018, HI16-01, HI16-018, HI10-20, HI10-208, HI36-02, HI36-028, HI36-03, HI36-038, HI36-05, HI36-058, HI36-06, HI36-068, HI36-07, HI36-078, HI36-08, HI36-088, HI20-01, HI20-018, HI19-01, HI19-018, HI28-01, HI28-018, HI15-01, HI15-018, HI21-01, HI21-018, HI36-01, HI36-018, HI36-04, HI36-048, HI23-01, HI23-018, HI25-01, HI25-018, HI31-01, HI31-018, HI34-201, HI34-218	
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