



CE Technical Documentation
Ultrasonic scaler tips

File No: CE-TD-01-7.1

Rev. No: A/2

EC Declaration of Conformity

According to Regulation (EU) Directive 93/42/EEC (MDD) Article 120

Rev. No.	Revision history	Approved by	Date
A/0	Update all documents according to Regulation (EU) 2017/745	Jims	2022.04.16
A/1	Updated by NB required.	Huang Ming Hui	2024.12.25
A/1	Adjust the model	Huang Ming Hui	2025.5.25
A/2	Add a description of the compliance status	Yang Ai Juang	2026.06.08

Complied by:	Yang Ai Juang	Date:	2026.06.08
Reviewed by:	Jin Tao	Date:	2026.06.08
Authorized by:	Jims	Date:	2026.06.08

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EC Declaration of Conformity

Manufacturer: Guilin Yikeshi Medical Instrument Co. Ltd.

Address: D08, High Tech Industrial Park, Chaoyang Rd, Qixing, Guilin, Guangxi 541004, China.

SRN: CN-MF000019045

EC representative: Xpedent Austria GmbH

Address: Millennium Park 9 6890 Lustenau Sitz in politischer Gemeinde Lustenau Austria

SRN: AT-AR-000003164

Product Trade Name: Xpedent ultrasonic scaler tips

Product Common Name: Ultrasonic scaler tips

Intended use: Ultrasonic Scaler Tips are indicated used for commonly scaling to remove hard (dental calcium), deposits from the teeth in a range of clinical dental procedures including general (scaling-prophylaxis), periodontal, endodontic.

Basic UDI-DI: Please refer to Annex 1 in the next page

EMDN code: Q010199-CONSERVATIVE DENTISTRY AND ENDODONTICS DEVICES - OTHER

Model: Please refer to Appendix 1 in the next page

Classification: According to Annex VIII, Rule 7 of (EU) 2017/745 (MDR), the Ultrasonic scaler tips is in class IIa.

Conformity Assessment Route: Chapters I and III of Annex IX, Regulation (EU) 2017/745 (MDR).

Certificate No.: CN19/41132 (NB 1639), valid until 26 May 2024 by original term, extended to 31 December 2028 under Reg (EU) 2023/607.

Transitional Status & Compliance Statement

This product is placed on the market as a legacy device under the transitional provisions of Article 120(3) MDR as amended by Regulation (EU) 2023/607.

The certificate's validity is deemed extended to 31 December 2028 under Article 120(2), because the MDR application and written agreement with NB 1639 were lodged by the expiry date (per the SGS confirmation letter ref. CLNB1639 – CN/GGX/CAN15440 dated 12 May 2023)

Currently, the manufacturer has signed an MDR conformity assessment agreement with the Notified Body SGS Belgium NV (NB 1639) and has initiated the formal MDR certification process. According to the confirmation letter issued by SGS, the manufacturer's Quality Management System has been established and is effectively operating in accordance with MDR requirements, and the MDR technical documentation is currently under assessment by the Notified Body. conformity is currently declared on the basis of Directive 93/42/EEC (the extended certificate), with MDR assessment in progress; the DoC will be reissued on the MDR basis once the MDR certificate issues.

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The product conforms to Directive 93/42/EEC, while the MDR post-market surveillance, vigilance and registration obligations under Article 120(3) apply. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances are incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body 1639, SGS Belgium NV, TSGS House Noorderlaan 87 2030 Antwerp Belgium.

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer:
Guilin Yikeshi Medical Instrument Co. Ltd..

Signed for and behalf of: Guilin Yikeshi Medical Instrument Co. Ltd.

Name: 

Title: CEO

Date: 08-06-2026

Location: Guilin





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Annex 1: Models and Basic UDI-DI list

Basic-UDI-DI		
697121991101HY		
G1、G2、G3、G4、G5、 G6、G7、G8、eA、eP、 ePS、ePL3 ICPpeek、GD1、GD2、 GD3、GD4、GD5、GD6、 GD7、GD8 s#1、S#2、S#3、s#1S、 s10X、s10P、s10Z、GN1、 GN2、GN3、GN4、GN5、 GN6、GN7、GN8、GS1、 GS2、GS3、GS4、GS5、 GS6、GS7、sr1L、sr2L、 sr3L、sr4L、srPE1、srPE2、 srPE3、GK1、GK2、GK3、 GK4、GK5、GK6、GK7、 GK11、k#5、k#6、k#7、 k#8、k#60、k#61、k#62、 k5A、GM1、GM3、GM4、 GM5、GM6、S3、S6、 GC1、GC2、GK1(B)、GK2 (B)、GK3 (B)、GK4(B)、 GK1 (C)、GK2 (C)、GK3 (C)、GK4(C)、a37、a38、 a39、a32、NK1、NK2、 NK3、NK4、NK5、NK6、 NK7、nS1、nS2、nS3、 k6A、k7A、k8A、k60A、 k61A、GK5A、K201、 K202、K203	P1、P3、P2L、P2R、 P2LD、P2RD、P3D P4、P4D、eH3、P6L P6R、XE-PTU、XE-PRT XE-HA、XE-HC、XE- PTR、XE-PTL、XE-SU1、 XE-SLB、XE-SU4、XE- SU5、XE-SU2、PD1、 PD3、PD2L、PD2R、 PD2LD、PD2RD、PD3D、 PD4、PD4D、PD6L、 PD6R、sH1、sH3、SH4L、 sH4R、sICP、STK1S、 STK1L、sTK2L、STK2R、 PTU、PRT、HA、PN1、 PN3、PN2L、PN2R、 PN2LD、PN2RD、PN3D、 PN4、PN4D、nSICP、 PS4、PS3D、PS4D、 PS2L、PS2R、PS2LD、 PS2RD、srICP、PS1、 PS3、XK-SFS100、XK- SFS101、XK-SFS102、XK- SFS105、XK-SFS109、 PM1、PM3、PM4、eICP、 P50L、P50R、P52、P53L、 P53R、P59、P56、P54L、 P54R、PC1、PSTO、 PSTU、PSTI、kICP、 kICPA、XD-PM1、XD- PM2、XD-PM3、XD- PM4、XS-PFU、XS-PFL、 XS-PFR	E1、E2、E3、E3D、E4、 E4D、E5、E5D、E8、E9、 E10、E10D、E11、E11D、 E14、E14D、E15、E15D、 E16、ED1、ED2、ED3、 ED3D、ED4、ED4D、 ED5、ED5D、ED8、ED9、 ED10、ED10D、ED11、 ED11D、ED14、ED14D、 ED15、ED15D、EN1、 EN2、EN3、EN3D、EN4、 EN4D、EN5D、EN8、 EN9、EN10、EN10D、 EN11、EN11D、EN14、 N14D、EN15、EN15D、 sET40D、ES1、ES2、ES3、 ES3D、ES4、ES4D、ES5、 ES5D、EK8、EM1、EM3、 EM3D、EM9、GEBD-1、 GEBD-2、GEFD-1、GEFD- 2、GE20、GE20D、 GE40D、UCT、S70D、 SET20-4D、CT-4、SAD、 SPL、SPLD、SPR、SPRD、 S90、S90D、SMLD、 SMRD、HFL、HFR、 MINI7、XE-GEBD1、XE- GEBD2、XE-GEFD1、XE- GEFD2、XE-GE20、XE- GE20D、XE-GE40D、XE- UCT、XE-S70D、XE- SET20-4D、XE-CT4、XE- SAD、XE-SPL、XE- SPLD、XE-SPR、XE- SPRD、XE-S90、XE- S90D、XE-SMLD、XE- SMRD、XE-HFL、XE- HFR、XE-MINI7