

CERTIFICATE OF CONFORMITY



Holder of Certificate & Manufacturer Name & Address :

Name	Shenzhen Ainengke Electronics Co., Ltd.
Address	Jinshenghui Technology Park, Dafu Industrial Zone, Guanlan Street, Longhua District, Shenzhen City.

European Representative:

Name: REP Europe GmbH

Add: Prinzenallee 7, 40549, Düsseldorf, Germany

SRN: DE-AR-000025090

Based on our assessment we confirm that the Technical File of the product is in accordance with the technical requirements of the above standards and hence fulfills the technical requirements of the

Product:	Electric Tooth Cleaner
Model:	T4, T5, T6, T7, T8, T9, T10, M1, M2, M3, M4;
Directive	Regulation (EU) 2017/745 on Medical Devices (MDR) Class I, Non-sterile, No measuring function(Annex VIII, Rule 13)
Reference standards:	EN ISO13485:2016 ,EN ISO14971:2019 ,EN ISO 12870:2018, EN IEC 60601-2-83: 2020/A11 :2021

After preparation of the necessary technical documentation as well as the EU declaration of conformity the required CE marking can be affixed on the product. The declaration of conformity is issued under the sole responsibility of the manufacturer. Other relevant EU-directives have to be observed.

Certificate Number: UNICO-CE-M2025XS5728

Issue Date: February 18, 2025

Expiry Date: February 17, 2030



APPROVE

UNICO CERTIFICATION TESTING CO., LTD

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