



EU Declaration of Conformity

Manufacturer:

Company Name: Shining 3D Tech Co., Ltd.
Address: No. 1398 Xiangbin Road, Wenyan,
Xiaoshan, Hangzhou, Zhejiang, China
Tel: +86 571 8299 9050
Email: sales@shining3d.com
SRN No.: CN-MF-000008402

Whose Authorized Representative:

Company Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
SRN No.: NL-AR-000000121

Product Name	Intraoral Scanner		
Model	Aoralscan Elite		
Intended Use	This is an intraoral scanner that works with the supplied software programs. By performing scanning directly and digitally acquiring and saving the 2D/3D color images of teeth, gingiva and oral mucosa, the scanner is available for patients with needs of orthodontic, implant, and restoration.		
Basic UDI-DI	697016308AoralscanEVR	Classification and rule	Class I, Rule 13
GMDN Code	38597	EMDN (CND) Code	Q0199
Conformity Assessment Route	Article 52, §7, Annex II and Annex III of the REGULATION 2017/745/EU		

This declaration of conformity is issued under the sole responsibility of the Legal Manufacturer.

We, the manufacturer, hereby declare that the product mentioned above complies with the following European Regulation and Directives with amendments:

- Medical Device Regulation 2017/745/EU

The applied harmonized standards and common specifications for the specified products in this Declaration of Conformity are listed in the technical documentation. We agree to develop, implement and maintain a documented post-production monitoring process.

Shining 3D Tech Co., Ltd.

Place: Hangzhou, China

Issued Date: May 15, 2024

Signature: 

Title: Chief Executive Officer

Expiration Date: May 14, 2026

