



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	3D Face Scanner		
Model	MetiSmile		
Intended Use	The product uses optical scanning method to collect facial 3D data and jaw movement tracking data to provide 3D digital models for facial and oral CAD design.		
Basic UDI-DI	697016308MetiSmilePF	Classification and rule	Class I, Rule 13
GMDN Code	47556	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
- Waste Electrical & Electronic Equipment Directive (WEEE) 2012/19/EU
- RoHS Directive 2011/65/EU and Commission Delegated Directive (EU) 2015/863
- Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation 1907/2006/EC

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: August 18, 2023

Signature:

Title: Chief Executive Officer

Expiration Date: August 17, 2025

