



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

Whose Single Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Intraoral Scanner	Model	Aoralscan3 Opera Mach 2 Intelliscan 3X ez2scan
Intend use	This is an intraoral scanner that works with the supplied software programs. With Intraoral Scanner, you can perform intraoral scanning directly and digitally acquire and save the 2D/3D color images of a patient's teeth and gingiva for orthodontic, implant, and restoration usage.		
Classification and rule	I, rule 13		
Conformity Assessment Route	Article 19, Annex II, Annex III and Annex IV		

Conformity Assessment Route: Annex VII of the REGULATION (EU) 2017/745.**Applicable Standards:***ISO 13485:2016**EN ISO 14971:2019**EN 62366-1:2015**ISO 15223-1:2021**BS ISO 20417:2021**ISO 10993-1:2018**ISO 10993-10:2010**ISO 10993-5:2009**IEC 60601-1-2:2014**IEC 60825-1:2014**IEC 60601-1:2005+AMD1:2012 CSV*

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Shining 3D Tech Co., Ltd.**Position held in the company:** General
Manager**Place:** Hangzhou, China**Signature:****Date:** January 12, 2022**Seal/Stamp:**