



SHINING 3D
DENTAL

EU Declaration of Conformity

Manufacturer:

Company Name:

Hangzhou SHINING3D Dental Technology Co., Ltd.

Address: 9-5-2, Tri-River Valley, Wenyan Street,
Xiaoshan, Hangzhou, Zhejiang, China

Tel: +86 571 8299 9050

Email: sales@shining3d.com

SRN No.: CN-MF-0000033456

Whose Authorized Representative:

Company Name:

Lotus NL B.V.

Address: Koningin Julianaplein, 40, 1e Verd, 2595AA,
The Hague, Netherlands.

E-mail: peter@lotusnl.com

SRN No.: NL-AR-000000121

Product Name	Splint Hard Resin		
Model	SH01		
Intended Use	SH01 is a light-curable resin for the additive manufacturing of individual dental bite splints.		
Basic UDI-DI	697533870SH01NM	Classification and rule	Class I, Rule 5
GMDN Code	16730	GMDN (CND) Code	Q010699
Conformity Assessment Route	Article 52, §7, Annex I 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
- 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-market surveillance process.

Hangzhou SHINING3D Dental Technology Co., Ltd.

Place: Hangzhou, China

Issued Date: April 10, 2024

Signature:

Title: Executive Director

Expiration Date: April 09, 2026