EU Declaration of Conformity

Declaration of Conformity
for Dental Tray Resin

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices as amended by Regulation (EU) 2020/561

The undersigned declares that the products described in this document meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This EU Declaration is issued under the sole authority of the manufacturer.

General Product Name:	Dentifix-3D Dental Tray Resin
Manufacturer:	Resine-3D 83 rue des mines innovantes 59860, Bruay-sur-l'Escaut, France
Manufacturer's SRN:	98217207400014
SKU Number:	3760424700500
Variants	None
Intended Purpose:	Photopolymer resin intended for 3D printing of custom dental trays
MDR Classification	Class I by Annex VIII, Rule 5, 1st Paragraph, 2nd Indent
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
Medical Device Regulation Assessment Route	According to Article 52(7)

Name: **Mina Aboulsaad** **Position: Chief Technical Officer**

Signed: Mina A. Saad **Date:** 14/04/2025

This Declaration of Conformity is issued in Bruay-sur-l'Escaut, France on behalf of Resine-3D SAS.

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Appendix I – Applicable Common Specifications

This present declaration is also in conformity with the following Common Specifications:

Common Specification	Description
N/A	Not Applicable

Appendix II – Applicable Consensus Standards

This present declaration is also in conformity with the following Consensus Standards:

Standard	Description
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15233-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 13485:2016/AC:2018	Medical devices — Quality management systems — Requirements for regulatory purposes

Version History

Version	Complied By	Date	Description
01	M. ABOULSAAD	14 April 2025	First version

RESINE-3D
Citadelle des Savoir-Faire
83 rue des Mines Innovantes
59860 Bruay-sur-l'Escaut France
Siret : 98217207400014