

EC Declaration of Conformity – TrueDent

According to Annex IV of the Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017, concerning medical devices, we **Stratasys Ltd. (the manufacturer)** hereby declare that the medical device specified below meets the provision of the Regulation (EU) 2017/745 for medical devices. This declaration is supported by the Quality System approval by the Notified Body, ISO 13485:2016 Certificate No. Q5 120984 0002 Rev. 00. All supporting documentation is retained at the premises of the manufacturer.

Manufacturer Name: Stratasys Ltd.
Manufacturer Address: 1 Holtzman St., Science Park, Rehovot, 7670401, Israel
Manufacturers SRN: IL-MF-000040298
Authorized Representative Name: Stratasys GmbH
Authorized Representative Address: Airport Boulevard B 120, 77836 Rheinmünster, Germany
Authorized Representative SRN: DE-AR-000039118
Basic UDI-DI: 7290018915TrueDentRB
Name of the Device: TrueDent®
Intended purpose: TrueDent is a light-curable resin intended for the fabrication of dental appliances, including removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers. The material serves as an alternative to traditional heat-curable and auto-polymerizing resins and is intended exclusively for professional dental work. All TrueDent devices are intended for long-term intraoral use (>30 days). TrueDent is intended for adult patients with a total or partial loss of teeth within one or both jaws.
Classification: Class IIa according to Rule 8 in Annex VIII of the Medical Device Regulation.
Notified Body Name and ID: TÜV SÜD Product Service GmbH (NB #0123)
CE Certificate Number: Certificate No. G15 120984 0001 Rev. 00
Conformity assessment route: Conformity assessment was performed according to Annex IX, Chapter I and III of the Medical Device Regulation.

This declaration of conformity is issued under the sole responsibility Stratasys Ltd.

Signature:



Place and date of issue:

Israel, 01-Feb-2026

Name: Amir Kleiner

Title: COO

Attachment to the declaration of conformity TrueDent

Device	Description	Part Number	Classification	Basic UDI-DI	EMDN code
TrueDent®	TrueDent Clear, TDM100	OBJ-09164	IIa	7290018915TrueDentRB	Q010699
	TrueDent White, TDM110	OBJ-09168			
	TrueDent Cyan, TDM120	OBJ-09165			
	TrueDent Magenta, TDM130	OBJ-09166			
	TrueDent Yellow, TDM140	OBJ-09169			