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Stratasys TrueDent Becomes the First High-esthetic, Monolithic 3D-printed Denture Solution to Achieve Certification in Europe, a $2 Billion+ Market

The CE Class IIa certification of TrueDent® resins expands patient access to digitally produced dentures and temporary restorations while supporting scalable adoption across European laboratories

MINNETONKA, Minn. & REHOVOT, Israel--(BUSINESS WIRE)-- Stratasys Ltd. (NASDAQ: SSYS) today announced that its TrueDent® resins have received CE marking as a Class IIa medical device, making them Europe's first high-esthetic, monolithic 3D-printed denture solution to achieve certification in the more than $2 billion market. This milestone enables broader regulated clinical use and expands patient access to polychromatic, monolithic 3D-printed dentures, removable partial dentures, and crowns and bridges.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20260317920719/en/

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The expanded indication now includes intraoral removables for long-term use of more than 30 days as well as crowns and bridges, allowing dental laboratories to address a wider range of restorative cases through a single, integrated digital workflow. As European providers continue scaling digital denture production, the certification supports broader clinical adoption while strengthening the commercial foundation for growth across the region.

According to a 2024 iData report[1], the demand for denture solutions in Europe continues to grow as the region's opportunity for dentures is projected to expand from USD 2.19 billion in 2023 to USD 2.45 billion by 2028.

Under the European Medical Device Regulation (MDR), Class IIa devices are subject to an independent third-party oversight and heightened regulatory scrutiny. For laboratories and clinicians, this classification reflects the regulatory standard commonly expected for restorative dental materials, strengthening confidence in routine clinical use and supporting broader market adoption across the region.

TrueDent-D™ was introduced in Europe in early 2025 under a CE Class I designation for denture production. While removable dentures are permitted under Class I, achieving CE

Class IIa certification for TrueDent expands the indications and positions Stratasys to further penetrate the regulated European restorative market. It also gives dental labs, clinics, and patients even greater confidence in the validated biocompatibility, manufacturing controls, traceability and clinical safety and performance of the certified TrueDent resins.

"Achieving CE Class IIa certification for TrueDent is an important milestone and supports the continued expansion of our dental business in Europe," said Chris Kabot, Vice President Dental, Stratasys. "By aligning TrueDent with the regulatory classification customers know and expect, we are providing additional clarity and confidence for clinicians and laboratories as they expand digital denture and temporary restoration workflows across the region."

The transition to CE Class IIa requires no changes to print settings, formulation, workflow, or shelf life on the Stratasys J5 DentaJet® printer platform. A defined conversion kit enables existing customers to move seamlessly from TrueDent-D to TrueDent certified resins, preserving established production processes and outcomes.

TrueDent resin colors include: TrueDent® White , TrueDent® Clear, TrueDent® Cyan, TrueDent® Magenta, TrueDent® Yellow. For more information about the TrueDent digital denture application, visit the Stratasys TrueDent page.

[1] – iData Europe Market Report Suite for Dental Prosthetics, February 2024

About Stratasys

Stratasys is leading the global shift to additive manufacturing with innovative 3D printing solutions for industries such as aerospace, automotive, consumer products, and healthcare. Through smart and connected 3D printers, polymer materials, a software ecosystem, and parts on demand, Stratasys solutions deliver competitive advantages at every stage in the product value chain. The world's leading organizations turn to Stratasys to transform product design, bring agility to manufacturing and supply chains, and improve patient care.

To learn more about Stratasys, visit www.stratasys.com, the Stratasys blog, X/Twitter, LinkedIn, or Facebook. Stratasys reserves the right to utilize any of the foregoing social media platforms, including Stratasys' websites, to share material, non-public information pursuant to the SEC's Regulation FD. To the extent necessary and mandated by applicable law, Stratasys will also include such information in its public disclosure filings.

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