

DEVICE AVAILABILITY UNDER MDR

Date: 21 June 2021

Formlabs, Inc. hereby certifies that the medical devices listed on Page 2 can be used and sold in accordance with the EU MDR¹.

According to the EU MDR Article 120, Paragraph 4, devices lawfully placed on the market pursuant to Directive 93/42/EEC (MDD) by virtue of a valid certificate (valid until the end of the period indicated on the certificate) may continue to be made available on the market or put into service until 27 May 2025.



Sam Murray
Director, Regulatory Affairs and Quality Assurance

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Device (most current version)

Product Name	Catalog Code	SKU	93/42/EEC (MDD) Certificate Expiry	Manufacturer
Dental LT Clear Resin	FLDLCL01	RS-F2-DLCL-01	17 December 2023	Vertex Dental BV
Denture Base LP	FLDBLP01	RS-F2-DBLP-01	28 March 2024	Dentca Inc
Denture Base OP	FLDBOP01	RS-F2-DBOP-01	28 March 2024	Dentca Inc
Denture Base RP	FLDBRP01	RS-F2-DBRP-01	28 March 2024	Dentca Inc
Denture Base DP	FLDBDP01	RS-F2-DBDP-01	28 March 2024	Dentca Inc
Denture Teeth A1	FLDTA101	RS-F2-DTA1-01	28 March 2024	Dentca Inc
Denture Teeth A2	FLDTA201	RS-F2-DTA2-01	28 March 2024	Dentca Inc
Denture Teeth A3.5	FLDTAS01	RS-F2-DTAS-01	28 March 2024	Dentca Inc
Denture Teeth B1	FLDTB101	RS-F2-DTB1-01	28 March 2024	Dentca Inc
Denture Teeth A3	FLDTA301	RS-F2-DTA3-01	28 March 2024	Dentca Inc
Denture Teeth B2	FLDTB201	RS-F2-DTB2-01	28 March 2024	Dentca Inc
Temporary CB A2	FLTCA201	RS-F2-TCA2-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Temporary CB A3	FLDTA301	RS-F2-DTA3-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Temporary CB B1	FLDTB201	RS-F2-DTB2-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Temporary CB C2	FLTCC201	RS-F2-TCC2-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Permanent Crown A2	FLPCA201	RS-F2-PCA2-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Permanent Crown A3	FLPCA301	RS-F2-PCA3-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Permanent Crown B1	FLPCB101	RS-F2-PCB1-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Permanent Crown C2	FLPCC201	RS-F2-PCC2-01	26 May 2024	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG