

EC CERTIFICATION

EU Quality Management System Certificate Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Formlabs Ohio Inc.

27800 Lemoyne Road, Millbury, Ohio, 43447, United States

Manufacturer SRN: US-MF-000002761

Authorised Representative:

Advena Ltd

Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta

Scope:

Non-active, Non-implantable Dental fabrication materials, class IIa.

Certificate Number:

28620124904

Revision:

03

Initial Certification Date:

13 June 2022

Certificate Decision Date:

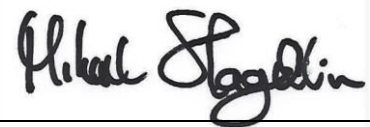
9 March 2026

Certificate Issue Date:

9 March 2026

Certificate Expiry Date:

12 June 2027



Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	TD00051-01 Formlabs Ohio Inc. Dental LT Clear V2 Resin
Last Audit Report Reference	Stage 1 - ACTY-2022-524350
	Stage 2 - ACTY-2022-524351
Change Notice Reference	CN00051-002
	CN00051-009
	MISC00051-001

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
8620124904	13 June 2022	Initial certificate
8620124904-01	30 August 2023	Address change
8620124904-02	20 February 2026	Address correction
8620124904-03	9 March 2026	Correction of certificate history



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PRODUCT LIST FOR CERTIFICATE

Issued to: Formlabs Ohio Inc.

Certificate number: 28620124904-03

Certificate valid from: 2026-03-09

Product list issue date:
09 March 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Non-active, Non-implantable Dental fabrication materials, class IIa.			
Basic UDI-DI: 0850061175FLPTUH			
FLPTA201 - Premium Teeth Resin HT A2	Class IIa Q010699		2024-04-15
FLPTA301 - Premium Teeth Resin HT A3	Class IIa Q010699		2024-04-15
FLPTB101 - Premium Teeth Resin HT B1	Class IIa Q010699		2024-04-15
FLPTBL01 - Premium Teeth Resin HT Bleach	Class IIa Q010699		2024-04-15
Basic UDI-DI: 08600020993FLDLCOQL			
FLDLCO01 - Dental LT Comfort Resin	Class IIa Q010699		2023-11-28
FLDLCO11 - Dental LT Comfort Resin	Class IIa Q010699		2024-04-30
Basic UDI-DI: 8600020993FLDLCLQE			
FLDLCL02 - Dental LT Clear V2 Resin	Class IIa Q010699		2022-06-13

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
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