

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.

The Belport Company, Inc.

4825 Calle Alto, Camarillo, California, 93012, United States

Manufacturer SRN: US-MF-000044279

Authorised Representative Name

Llins Service & Consulting GmbH.

Heinigstrasse, 26 67059 Ludwigshafen, Germany

Scope:

Dental materials

Certificate Number:

28620216316

Revision:

00

Initial Certification Date:

18 July 2025

Certificate Decision Date:

18 July 2025

Certificate Issue Date:

18 July 2025

Certificate Expiry Date:

7 May 2030



Brian Mather
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	TD00095-007 OptiFlow II Flowable Composite
Audit Report Reference	Stage 1 audit ACTY-2019-387115
	Stage 2 audit ACTY-2022-569372
Change Notice Reference	CN00095-009

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620216316	18 July 2025	Initial Certificate



PRODUCT LIST FOR CERTIFICATE

Issued to: The Belport Company, Inc

Certificate number: 28620216316

Certificate valid from: 2025-07-18

Product list issue date:
10 June 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Dental materials			
Basic UDI-DI: 081874602480000H7			
450102 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
450103 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
450104 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
450105 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
450107 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
450115 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48201 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48202 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48203 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48204 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48205 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48206 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48207 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18

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
48209 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48210 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48211 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48212 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48213 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48214 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48215 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48216 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48217 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48220 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48221 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
48222 - OptiFlow II Flowable Composite	Class IIa Q01010103		2025-07-18
5723847 - Flowable composite A1	Class IIa Q01010103		2025-07-18
5723848 - Flowable composite A2	Class IIa Q01010103		2025-07-18
5723849 - Flowable composite A3	Class IIa Q01010103		2025-07-18
5723850 - Flowable composite A3.5	Class IIa Q01010103		2025-07-18
5723851 - Flowable composite B1	Class IIa Q01010103		2025-07-18
5723852 - Flowable composite B3	Class IIa Q01010103		2025-07-18
5723853 - Flowable composite C1	Class IIa Q01010103		2025-07-18
5723854 - Flowable composite C3	Class IIa Q01010103		2025-07-18
5723855 - Flowable Composite Kit	Class IIa Q01010103		2025-07-18

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Product	Classification and EMDN	Intended use ¹	Date Added
5723900 - Flowable composite	Class IIa Q01010103		2025-07-18
5723901 - Flowable composite	Class IIa Q01010103		2025-07-18
5723902 - Flowable composite	Class IIa Q01010103		2025-07-18
5723903 - Flowable composite	Class IIa Q01010103		2025-07-18
5723904 - Flowable composite	Class IIa Q01010103		2025-07-18
5723905 - Flowable composite	Class IIa Q01010103		2025-07-18
5723906 - Flowable composite	Class IIa Q01010103		2025-07-18
5723907 - Flowable composite	Class IIa Q01010103		2025-07-18
5723908 - Flowable Composite Kit	Class IIa Q01010103		2025-07-18
9796980 - Flowable composite A1	Class IIa Q01010103		2025-07-18
9796981 - Flowable composite A2	Class IIa Q01010103		2025-07-18
9796982 - Flowable composite A3	Class IIa Q01010103		2025-07-18
9796983 - Flowable composite A3.5	Class IIa Q01010103		2025-07-18
9796984 - Flowable composite B1	Class IIa Q01010103		2025-07-18
9796985 - Flowable composite B3	Class IIa Q01010103		2025-07-18
9796986 - Flowable composite C1	Class IIa Q01010103		2025-07-18
9796987 - Flowable composite C3	Class IIa Q01010103		2025-07-18
9796988 - Flowable Composite Kit	Class IIa Q01010103		2025-07-18
Basic UDI-DI: 081874602630000GA			
24113 - Rodin RapidCeram, Shade 0M3, 1.2kg Bottle	Class IIa Q010699		2026-06-05
24114 - Rodin RapidCeram, Shade A1, 1.2kg Bottle	Class IIa Q010699		2026-06-05

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Product	Classification and EMDN	Intended use ¹	Date Added
24115 - Rodin RapidCeram, Shade A2, 1.2kg Bottle	Class IIa Q010699		2026-06-05
24116 - Rodin RapidCeram, Shade B1, 1.2kg Bottle	Class IIa Q010699		2026-06-05
24117 - Rodin RapidCeram, Shade 0M3, 600g Bottle	Class IIa Q010699		2026-06-05
24118 - Rodin RapidCeram, Shade A1, 600g Bottle	Class IIa Q010699		2026-06-05
24119 - Rodin RapidCeram, Shade A2, 600g Bottle	Class IIa Q010699		2026-06-05
24120 - Rodin RapidCeram, Shade B1, 600g Bottle	Class IIa Q010699		2026-06-05
24121 - Rodin RapidCeram, Shade 0M3, 300g Bottle	Class IIa Q010699		2026-06-05
24122 - Rodin RapidCeram, Shade A1, 300g Bottle	Class IIa Q010699		2026-06-05
24123 - Rodin RapidCeram, Shade A2, 300g Bottle	Class IIa Q010699		2026-06-05
24124 - Rodin RapidCeram, Shade B1, 300g Bottle	Class IIa Q010699		2026-06-05
24125 - Rodin RapidCeram, Shade 0M1, 1.2kg/Bottle	Class IIa Q010699		2026-06-05
24126 - Rodin RapidCeram, Shade A3, 1.2kg/Bottle	Class IIa Q010699		2026-06-05
24127 - Rodin RapidCeram, Shade C2, 1.2kg/Bottle	Class IIa Q010699		2026-06-05
24128 - Rodin RapidCeram, Shade B2, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24129 - Rodin RapidCeram, Shade B3, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24130 - Rodin RapidCeram, Shade B4, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24131 - Rodin RapidCeram, Shade A3.5, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24132 - Rodin RapidCeram, Shade A4, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24133 - Rodin RapidCeram, Shade C1, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24134 - Rodin RapidCeram, Shade C3, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24135 - Rodin RapidCeram, Shade C4, 1.2kg/bottle	Class IIa Q010699		2026-06-05

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Product	Classification and EMDN	Intended use ¹	Date Added
24136 - Rodin RapidCeram, Shade D2, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24138 - Rodin RapidCeram, Shade D4, 1.2kg/bottle	Class IIa Q010699		2026-06-05
24139 - Rodin RapidCeram, Shade 0M1, 600g/Bottle	Class IIa Q010699		2026-06-05
24140 - Rodin RapidCeram, Shade A3, 600g/Bottle	Class IIa Q010699		2026-06-05
24141 - Rodin RapidCeram, Shade C2, 600g/Bottle	Class IIa Q010699		2026-06-05
24142 - Rodin RapidCeram, Shade B2, 600g/Bottle	Class IIa Q010699		2026-06-05
24143 - Rodin RapidCeram, Shade B3, 600g/Bottle	Class IIa Q010699		2026-06-05
24144 - Rodin RapidCeram, Shade B4, 600g/Bottle	Class IIa Q010699		2026-06-05
24145 - Rodin RapidCeram, Shade A3.5, 600g/Bottle	Class IIa Q010699		2026-06-05
24146 - Rodin RapidCeram, Shade A4, 600g/Bottle	Class IIa Q010699		2026-06-05
24147 - Rodin RapidCeram, Shade C1, 600g/Bottle	Class IIa Q010699		2026-06-05
24148 - Rodin RapidCeram, Shade C3, 600g/Bottle	Class IIa Q010699		2026-06-05
24149 - Rodin RapidCeram, Shade C4, 600g/Bottle	Class IIa Q010699		2026-06-05
24150 - Rodin RapidCeram, Shade D2, 600g/Bottle	Class IIa Q010699		2026-06-05
24152 - Rodin RapidCeram, Shade D4, 600g/Bottle	Class IIa Q010699		2026-06-05
24153 - Rodin RapidCeram, Shade 0M1, 300g/Bottle	Class IIa Q010699		2026-06-05
24154 - Rodin RapidCeram, Shade A3, 300g/Bottle	Class IIa Q010699		2026-06-05
24155 - Rodin RapidCeram, Shade C2, 300g/Bottle	Class IIa Q010699		2026-06-05
24156 - Rodin RapidCeram, Shade B2, 300g/Bottle	Class IIa Q010699		2026-06-05
24157 - Rodin RapidCeram, Shade B3, 300g/Bottle	Class IIa Q010699		2026-06-05
24158 - Rodin RapidCeram, Shade B4, 300g/Bottle	Class IIa Q010699		2026-06-05

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Product	Classification and EMDN	Intended use ¹	Date Added
24159 - Rodin RapidCeram, Shade A3.5, 300g/Bottle	Class IIa Q010699		2026-06-05
24160 - Rodin RapidCeram, Shade A4, 300g/Bottle	Class IIa Q010699		2026-06-05
24161 - Rodin RapidCeram, Shade C1, 300g/Bottle	Class IIa Q010699		2026-06-05
24162 - Rodin RapidCeram, Shade C3, 300g/Bottle	Class IIa Q010699		2026-06-05
24163 - Rodin RapidCeram, Shade C4, 300g/Bottle	Class IIa Q010699		2026-06-05
24164 - Rodin RapidCeram, Shade D2, 300g/Bottle	Class IIa Q010699		2026-06-05
24166 - Rodin RapidCeram, Shade D4, 300g/Bottle	Class IIa Q010699		2026-06-05



Mikael Hagelin
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