

1. Purpose

The purpose of this specification is to determine the conditions which must be fulfilled by Superpont C+B - a heat cured crown and bridge resin for pressure curing - before releasing it for despatch. This specification is one of the registration documents and is used as a reference document when contacting the purchasers.

2. Product Characteristics

Superpont C+B, a heat-cured crown and bridge resin, is used in dentistry for the preparation of crowns and bridges, facets and intermediate bridge pieces through direct modelling and curing in pressurised containers. It comes into long term contact with human tissue. It is manufactured in cervical shades in VITA™ system: A3.5, A4, B2, B3, C4, D2, D4, dentine shades in VITA™ system: A1, A2, A3, A3.5, A4, B2, B3, B4, C2, C3, C4, D2, D3, D4, enamel shades in VITA™ system: A2, A3.5, B2, C4, D2, D4 and shade T (transparent).

3. Abbreviations

JJ	Quality Assurance
JKJ	Quality Assurance and Quality Control
OKJ.....	Quality Control Department
OVD	Documentation Department
PVJ	Quality Assurance and Control Section
SOP	Standard Operational Procedure
SP	Specification
ZP	Testing Procedure

4. Description

4.1 Product Name

SUPERPONT C+B

heat cured crown and bridge resin for pressure curing

4.2 Material Form, Shades

Superpont C+B powder is a fine powder, free from any mechanical impurity, in VITA™ shades A1, A2, A3, A3.5, A4, B2, B3, C2, C3, D2, D3, D4 and shade T. The colour shades are specified for cured resins and must conform to the standard colour guides.

Superpont C+B liquid is a clear or light yellowish liquid, free from mechanical impurity.

4.3 Package Size and Type

Superpont C+B set – large package:

8x20 g of powder in cervical shades in VITA™ system: A3.5, A4, B2, B3, C4, D2, 2xD4

14x20 g of powder in dentine shades in VITA™ system: A1, A2, A3, A3.5, A4, B2, B3, B4, C2, C3, C4, D2, D3, D4

1x20 g of powder in shade T (transparent)

7x20 g of powder in enamel shades in VITA™ system: A2, 2xA3.5, B2, C4, D2, D4 + 2x50 g of liq.

The powders are packed in plastic containers, the liquid in a glass vial. All are packed together in a case with an instruction sheet (user's guide), colour shade guide and pipettes.

Superpont C+B powder 100 g:

100 gr. of powder in 14 shades in VITA™ system: cervical, enamel, dentine and T (transparent), in a polyethylene container and a folded paper box with an instruction sheet (user's guide).

Superpont C+B liq. 250 gr.:

250 gr. of liquid in a glass vial and in a folded paper box with an instruction sheet (user's guide) and pipette.

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4.4 Collection of Samples: According to SOP 10-107, par. 5.1.

4.4.1 Number of counter-samples:

100 gr. of powder, 250 gr. of liquid from each finished product batch

4.5 The Product Must Conform to the Following Requirements

4.5.1 Contents of the package

Superpont C+B set – large package:

8x20 g of powder in cervical shades in VITA™ system: A3.5, A4, B2, B3, C4, D2, 2xD4: min. 8x18,2 g

14x20 g of powder in dentine shades in VITA™ system: A1, A2, A3, A3.5, A4, B2, B3, B4, C2, C3, C4, D2, D3, D4: min. 14x18.2 g

1x20 g of powder in shade T (transparent): min. 18.2 g

7x20 g of powder in enamel shades in VITA™ system: A2, 2xA3.5, B2, C4, D2, D4: min. 7x18.2 g + 2x50 g of liquid: min. 2x45.0 g

Superpont C+B powder 100 gr.

100 gr. of powder in 14 shades in VITA™ system: cervical, enamel, dentine and T (transparent): min. 95.5 g

Superpont C+B liq. 250 gr.: min. 241.0 g

4.5.2 Statistical product check: Conforms to SOP 10-107.

4.5.3 Other parameters

Tested property	Theory	Tested according to:
Homogeneity	conforms	ZP 3324111
Appearance and colour of the sample	conforms	ZP 3324111/ZP 3324400
Clarity and colour of the liquid	conforms	ZP 3324400
Opacity (neck, body, glaze) ±1.5% from standard	*	ZP 3324111
Delta E	*	ZP 3324111
Time required to produce a non-tacky plastic mixture	*	ZP 3324111
Bending strength	min. 50 MPa	ZP 185322
Brinell hardness	min. 130 MPa	ZP 185322
Absorbability	max. 32 µg/mm ³	ZP 185322
Solubility	max. 5 µg/mm ³	ZP 185322

4.6 Storage Conditions

To be stored in a dry place at temperatures of 5-25 °C, in a well sealed inner package. Keep the container in a well ventilated place away from sources of ignition, no smoking.

4.7 Shelf Life: 4 years

5. Related Documents

SOP 05-101	Rules for preparation of controlled documentation Level III
SOP 10-107	Rules for statistical check of products placed in inner packaging and for statistical check of finished products
ZP 3324111	Superpont C+B powder 0
ZP 3324400	Superpont C+B liq.
ZP 185322	Resin TS 2084 (Lucite)

6. Revisions

Modifications to this specification are provided by the JKJ Manager according to SOP 05-101.

6.1 Revision Procedure:

Chapter No.	Description	Pages	Revision	Effective from
-	Complete issue of the G109 specification incl. Appendices.	6	1	1.6.2003
-	Addition of shades.	6	2	1.2.2005
-	Shades, size, type and contents of the package, composition, raw materials, distribution list.	6	3	22.5.2006
-	Packaging, testing, documentation, distribution list and abbreviations.	3 + 3	4	5.4.2011
-	Rename of raw material articles 144122 and 144125; specify of powder component. Revision of liq. Component, added article 124872. Distribution list modified.	3 + 2	5	

Name and Surname, position	Signature	Date
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