Final Product Specification	Nr.: **SP A101**	Revision: 5
ADHESOR		
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1. PURPOSE

The objective of this specification is to determine product requirements which must Adhesor comply with before release for distribution. This specification serves for communication with customers.

2. PRODUCT DESCRIPTION

This glass-ionomer Adhesor is a two–compound zinc phosphate cement in the form of powder and liquid. This self-curing material is clinically proven, highly reliable and easy to use material.

3. INDICATION FOR USE

This product is indicated for base layer material under amalgam and composite fillings, temporary fillings, crown and bridge bonding and root canal filling.

4. PRODUCT TRADENAME

ADHESOR™
Zinc Phosphate Cement

5. MATERIAL FORM

Adhesor powder is fine power, free from mechanical impurities, in two shades - Light (1) or Dark (2).

Adhesor liquid is clear, colourless solution, free of mechanical impurities.

6. PRODUCT PACKAGING

Adhesor *80 g plv. + 55 g liq.*	min. 75.5 g plv. min. 50.5 g liq.	80g of powder (shade 1 or 2) in glass bottle, 55g of liquid in PE bottle, dosing spoon and IFU in cardboard box
Adhesor *80 g plv.*	min. 75.5 g	80g of powder (shade 1 or 2) in glass bottle, dosing spoon and IFU in cardboard box
Adhesor *55 g liq.*	min. 50.5 g	55g of liquid in PE bottle, dosing spoon and IFU in cardboard box

7. PRODUCT REQUIREMENTS

Requirement	Target		Unit	Test Method
	BASE	LUTING		
Consistency	1.5 - 1.6 plv / 0.8 liq. 1.5 - 1.6 plv / 0.5 liq.	1.1 - 1.2 plv / 0.8 liq. 1.1 - 1.2 plv / 0.5 liq.	g/g g/ml	ZP 3111130 ZP 3111110
Mixing Time (at 23°C± 1 °C)	1:00 – 1:30		min	ZP 3111130 ZP 3111110
Working Time (at 23°C± 1 °C)	3:00 – 4:00	4:00 – 6:00	min	ZP 3111130 ZP 3111110
Setting Time (at 37°C)	6:00 – 8:30	7:00 – 9:30	min	ZP 3111130 ZP 3111110
Compressive strength	Min. 70		MPa	ZP 3111130 ZP 3111110
Film thickness	Max. 40		μm	ZP 3111110
Acid Erosion	Max 0.3		mm	ISO 9917-1
Acid-soluable arsenic and lead contents	As – Max. 2.0 Pb – Max. 100		mg/kg	ISO 9917-1
Powder mean diameter	8.0 – 9.3		μm	ZP 3111110
Disintegration	Max. 0.2		%	ZP 3111110
Appereance	Colour shade according standard		-	ZP 3111112
Microbiological Safety	Compliant to SOP 10-110		-	SOP 10-110

8. STORAGE CONDITIONS

To be stored in a dry and dark place at 5- 25 °C, in a well-sealed container.

9. SHELF LIFE

Product shelf life is 5 years from the date of manufacturing.

10. ABBREVIATIONS	
JKJ	Quality Control and Quality Assurance
liq.	liquidum (liquid)
plv.	pulvis (powder)
SOP	Standard Operating Procedure
SP	Specification
ZP	Testing Instruction

11. RELATED DOCUMENTS	
SOP 05-101	Level III controlled documentation
SOP 10-107	Statistical control of products in primary packaging and finished products
SOP 10-110	Microbiological testing and evaluation
ZP 3111130	Adhesor liq.
ZP 3111110	Adhesor unshaded plv.
ZP 3111112	Adhesor plv. shade 2
ISO 9917-1	Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements

12. REVISION SUMMARY

JKJ manager is responsible for specification modifications according to SOP 05-101.

Chapter No.	Description	Nr. of Pages	Revision	Date of issue
-	The full text of SP A101 including annexes	5	1	17.10.2002
-	Characteristics, package size, package content, testing parameters, storage conditions, distribution	5	2	27.8.2007

	list.			
-	Updated Chapter 3 deleted 4.4.2. Updated Chapter 6 and distribution list. Canceled shades No. 3 and 4; recalculated powder content, changed shade No. 2.	3 + 2	3	28.01.2016
4.3., 4.5.1.	Revision according to the actual template in MasterControl). Updated 4.3. (insert isn´t a part of package). Removed "N"from the package name in 4.5.1.	3	4	12.3.2021
-	New layout implemented, Translated to english Section **1. Purpose -** *,specification is part of registration documentation'* removed Section **2. Product description** updated to be in line with TF & IFU Section **3. Indication for Use** added Section **4. Product tradename** (orig. 4.1.) updated to be in line with TF Section **6. Product packaging** (orig. 4.3. and 4.5.1) section mergeded and updated to be in line with TF Sampling plan section (orig. 4.4.) and statistic control sections (orig. 4.5.2) removed Section **7. Product requirements** (orig. 4.5.3.) updated according to Design Input Summary Section **10. Abbreviations** (orig. 3.) updated Section Appendix (orig. 6.) removed Section **12. Revision summary** updated (orig. 7. and 7.1. sections merged) Section Distribution (orig. 9.) removed	4	5	The date of issue

13. APPROVAL
Master Control