

PRODUCT TECHNICAL SPECIFICATION



QUALITY SYSTEM FORM

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GENERAL PRODUCT DESCRIPTION:		EA7-PTS-KW-AUX /EN			
PRODUCT FAMILY		AUX-01 Dental auxiliary			
PRODUCT NAME		Sandbag			
PROJECT NUMBER (if Applicable)		N/A			
TF INDEX		KW-AUX-01/SAN/EN			
Revision	Date	Change Reference	Prepared By	Description of Change	
1	2021-11-09	N/A	Grzegorz Panas	The first issue of the document.	

Product name	SANDBAG 50/270
Reference number	TP05003
Physical form of the product	White or slightly gray free-flowing powder
Product Components	Pure aluminium oxide
Al₂O₃ content	Min. 99.55
Fe₂O₂ content	Max. 0.025%
SiO₂ content	Max. 0.05%
Granulation	50 µm/ 270 mesh
Package weight	3 kg

* Requirements of Factory Standard ZN-11/10 – “Pure aluminum oxide for sandblasters - abrasive material for sandblasters”

DESTINATION WARE:	Sandbag 50/270 is pure aluminium oxide for sandblasting units
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Product name	SANDBAG 110/150
Reference number	TP11003
Physical form of the product	White or slightly gray free-flowing powder
Product Components	Pure aluminium oxide
Al₂O₃ content	Min. 99.55
Fe₂O₂ content	Max. 0.025%
SiO₂ content	Max. 0.05%
Granulation	110 µm/ 150 mesh
Package weight	3 kg

* Requirements of Factory Standard ZN-11/10 – “Pure aluminum oxide for sandblasters - abrasive material for sandblasters”

DESTINATION WARE:	Sandbag 110/150 is pure aluminium oxide for sandblasting units
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PRODUCT TECHNICAL SPECIFICATION



QUALITY SYSTEM FORM

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Product name	SANDBAG 250/60
Reference number	TP25003
Physical form of the product	White or slightly gray free-flowing powder
Product Components	Pure aluminium oxide
Al ₂ O ₃ content	Min. 99.55
Fe ₂ O ₂ content	Max. 0.025%
SiO ₂ content	Max. 0.05%
Granulation	250 µm/ 60 mesh
Package weight	3 kg

* Requirements of Factory Standard ZN-11/10 – "Pure aluminum oxide for sandblasters - abrasive material for sandblasters"

DESTINATION WARE:	Sandbag 250/60 is pure aluminium oxide for sandblasting units
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THE MATERIALS ARE INTENDED FOR USE IN DENTAL PROSTHETICS AND IS NOT RECOMMENDED OR RECOMMENDED FOR OTHER USE.

The data contained in the data sheets are for informational purposes only. Potential consumers should personally verify the suitability of the product in their field.

Safety features on the back

SECURITY FEATURES

STORAGE

The product is sensitive to moisture. Store in a cool, dry place.

PRECAUTIONS

The product is non-toxic. Avoid dust formation.

In case of contact with eyes, rinse with water and consult an ophthalmologist.

FOR MORE INFORMATION, PLEASE REFER TO THE PRODUCT SAFETY INSTRUCTIONS

Approval of the Product Technical Specification

	Signature	Date
Grzegorz Panas R&D Manager		2021-11-09
Andrzej Cegliński QA/RC Manager		2021-11-09

EVERALL7 Sp. z o.o.
ul. Augustówka 14, 02-981 Warszawa
tel. 22 858 82 72
NIP 521-01-24-886, Regon 002028511

DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC
No. KW-AK11/V210/2021/E

Manufacturer:	<p align="center">Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (DUNS) - N/A</p>		
Authorized EU-representative:	Name of the site, Address of the site – N/A		
PRODUCT CODE / CATALOGUE NUMBER	NAME	Classification	Rule*
V210A1Z01	Villacryl STC Hot color A1 powder 80g + liquid 40ml	IIa	Rule 8
V210A2Z02	Villacryl STC Hot color A2 powder 80g + liquid 40ml	IIa	Rule 8
V210A3Z04	Villacryl STC Hot color A3.5 powder 80g + liquid 40ml	IIa	Rule 8
V210A3Z03	Villacryl STC Hot color A3 powder 80g + liquid 40ml	IIa	Rule 8
V210A4Z04	Villacryl STC Hot color A4 powder 80g + liquid 40ml	IIa	Rule 8
V210B1Z06	Villacryl STC Hot color B1 powder 80g + liquid 40ml	IIa	Rule 8
V210B2Z07	Villacryl STC Hot color B2 powder 80g + liquid 40ml	IIa	Rule 8
V210C2Z08	Villacryl STC Hot color C2 powder 80g + liquid 40ml	IIa	Rule 8
V210C4Z09	Villacryl STC Hot color C4 powder 80g + liquid 40ml	IIa	Rule 8
V210D2Z12	Villacryl STC Hot color D2 4 powder 80g + liquid 40ml	IIa	Rule 8
V210Z11	Villacryl STC Hot ZESTAW	IIa	Rule 8
V210L01	Villacryl STC Hot liquid 40 ml	IIa	Rule 8
V210L02	Villacryl STC Hot liquid 200 ml	IIa	Rule 8
Purpose of the product:	Heat-curing acrylic resin for crowns and bridges veneering		
GMDN Code :	38781 - Crown/bridge material, polymer based		
Classification rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC		
WE HEREWITH DECLARES THAT THE ABOVE MENTIONED PRODUCTS: - ARE IN CONFORMITY WITH THE ESSENTIAL REQUIREMENTS ESTABLISHED IN ANNEX I AND PROVISIONS OF THE EUROPEAN COUNCIL DIRECTIVE 93/42/EEC - MEDICAL DEVICES AS AMENDED BY THE DIRECTIVE 2007/47/EC. - ARE DESIGNED, MANUFACTURED, TESTED AND RELEASED FOR SALE IN ACCORDANCE WITH THE TECHNICAL DOCUMENTATION - ARE THE SUBJECT TO PROCEDURE SET OUT IN ANNEX II OF DIRECTIVE 93/42/EEC (EXCEPT CLAUSE 4); - THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DEDECLARATION OF CONFORMITY.			
Harmonized Standards applied:	EN ISO 13485 :2016 EN ISO 14971 :2012 EN ISO 14155:2011 EN 1041:2008+A1:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2009		
Technical standards ref.:	ISO 10477:2018 - Dentistry - Polymer-based crown and veneering materials		
EC certificate :	According to annex II excluding (4) of the Directive 93/42/EEC EC certificate No. PL19/1102977398 (valid until 24 May 2024) Notified Body: SGS Belgium N.V., Noorderlaan 87, BE-2030 Antwerpen, Belgium ID number: 1639		

 Place: Warsaw
 Date: 2021-06-28

 Signature: _____
 Andzej Ceglinski
 Quality Assurance and Regulatory Compliance Manager

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DOC - DECLARATION OF CONFORMITY



QUALITY SYSTEM FORM

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**DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/74
No: KW-AK02/V130/EN**

Manufacturer:	Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (SRN): -		
Authorized EU-representative:	Name of the site, Address of the site – N/A		
PRODUCT CODE / CATALOGUE NUMBER	NAME	Class	Rule*
V1300Z01	Villacryl S color 0 (100 g powder + 50 ml liquid)	I	5
V1300P01	Villacryl S color 0 powder 30g	I	5
V1300P13	Villacryl S color 0 powder 100g	I	5
V1300P08	Villacryl S color 0 powder 1kg	I	5
V130T4Z03	Villacryl S color T4 (100 g powder + 50 ml liquid)	I	5
V130T4P01	Villacryl S color T4 powder 30g	I	5
V130T4P16	Villacryl S color T4 powder 100g	I	5
V130T4P11	Villacryl S color T4 powder 1kg	I	5
V130V2Z04	Villacryl S color V2 (100 g powder + 50 ml liquid)	I	5
V130V2P01	Villacryl S color V2 powder 30g	I	5
V130V2P14	Villacryl S color V2 powder 100g	I	5
V130V2P09	Villacryl S color V2 powder 1kg	I	5
V130V3Z08	Villacryl S color V3 (100 g powder + 50 ml liquid)	I	5
V130V3P15	Villacryl S color V3 powder 100g	I	5
V130V3P10	Villacryl S color V3 powder 1kg	I	5
V130V4Z05	Villacryl S color V4 (100 g powder + 50 ml liquid)	I	5
V130V4P07	Villacryl S color V4 powder 30g	I	5
V130V4P12	Villacryl S color V4 powder 100g	I	5
V130V4P06	Villacryl S color V4 powder 1 kg	I	5
V130L08	Villacryl S liquid 12ml	I	5
V130L09	Villacryl S liquid 50 ml	I	5
V130L02	Villacryl S liquid 200 ml	I	5
V130L07	Villacryl S liquid 500 ml	I	5
Intended use of the product:	Self-curing acrylic resin for dentures repair		
* Classification rules	ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745		
Basic UDI-DI	590160212REPPF		
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX,. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.			
Harmonized Standards applied:	EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2018 EN ISO 10993-5:2009 ENISO10993-10:2013 EN ISO 10993-18:2009		
Technical standards ref:	EN ISO 20795-1:2013 - Dentistry - Base polymers - Part 1 - Denture base polymers		
EC certificate:	N/A		

Place: Warszawa

Date of issue: 2021-05-25

Signature: _____

Andrzej Cegliński

Quality Assurance and Rfegulatory Compliance Manager

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QUALITY SYSTEM FORM

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DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/74
 No: KW-AK07/V160/EN

Manufacturer:	Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (SRN): -
Authorized EU-representative:	Name of the site, Address of the site – N/A

PRODUCT CODE / CATALOGUE NUMBER	NAME	Class	Rule*
V160Z01	Villacryl Ortho liquid 250 ml + powder 500 g + 3x12 ml color concentrates red, yellow and blue	I	5
V1600P07	Villacryl Ortho powder 500 g	I	5
V1600P05	Villacryl Ortho powder 2 kg	I	5
V1600P06	Villacryl Ortho powder 4 kg	I	5
V160L03	Villacryl Ortho liquid 250 ml	I	5
V160L04	Villacryl Ortho liquid 500 ml	I	5
V160L02	Villacryl Ortho liquid 1 l	I	5
V180Z09	Villacryl Ortho color concentrate set red, yellow and blue 3x12 ml	I	5
V1802P01	Villacryl Ortho color concentrate yellow 50 ml	I	5
V1803P02	Villacryl Ortho color concentrate orange 50 ml	I	5
V1804P03	Villacryl Ortho color concentrate red 50 ml	I	5
V1805P04	Villacryl Ortho color concentrate raspberry 50 ml	I	5
V1806P05	Villacryl Ortho color concentrate violet 50 ml	I	5
V1807P06	Villacryl Ortho color concentrate green 50 ml	I	5
V1808P07	Villacryl Ortho color concentrate light green 50 ml	I	5
V1809P08	Villacryl Ortho color concentrate blue 50 ml	I	5

Intended use of the product: Acrylic resin for removable orthodontic appliances

* Classification rules	ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745
Basic UDI-DI	590160212ORTGP

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX,. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
 THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

Harmonized Standards applied:	EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-18:2009
Technical standards ref:	EN ISO 20795-2:2013 - Dentistry - Base polymers - Part 2 - Orthodontic base polymers
EC certificate:	N/A

Place: Warszawa
 Date of issue: 2021-05-25
 Signature: 
 Andrzej Cegliński
 Quality Assurance and Regulatory Compliance Manager

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**DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/74
No: KW-AK01/V100/EN**

Manufacturer:		<p align="center">Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (SRN): -</p>			
Authorized EU-representative:		Name of the site, Address of the site – N/A			
PRODUCT CODE / CATALOGUE NUMBER	NAME	Class	Rule*		
V1000P03	Villacryl H Plus 0 powder 4kg	I	5		
V1000P04	Villacryl H Plus 0 powder 750g	I	5		
V1000P06	Villacryl H Plus 0 powder 30g	I	5		
V1000Z02	Villacryl H Plus 0 powder 750g+ liquid 400ml	I	5		
V100T2Z07	Villacryl H Plus T2 powder 750g+ liquid 400ml	I	5		
V100T4P10	Villacryl H Plus T4 powder 4kg	I	5		
V100T4P11	Villacryl H Plus T4 powder 30g	I	5		
V100T4Z08	Villacryl H Plus T4 powder 750g+ liquid 400ml	I	5		
V100V2P10	Villacryl H Plus V2 powder 4kg	I	5		
V100V2P17	Villacryl H Plus V2 powder 2kg	I	5		
V100V2P18	Villacryl H Plus V2 powder 750g	I	5		
V100V2P19	Villacryl H Plus V2 powder 300g	I	5		
V100V2P20	Villacryl H Plus V2 powder 30g	I	5		
V100V2Z09	Villacryl H Plus V2 powder 750g+ liquid 400ml	I	5		
V100V2Z11	Villacryl H Plus V2 powder 300g+ liquid 150ml	I	5		
V100V3Z11	Villacryl H Plus V3 powder 750g+ liquid 400ml	I	5		
V100V4P13	Villacryl H Plus V4 powder 2kg	I	5		
V100V4P14	Villacryl H Plus V4 powder 4kg	I	5		
V100V4P15	Villacryl H Plus V4 powder 750g	I	5		
V100V4P16	Villacryl H Plus V4 powder 300g	I	5		
V100V4P17	Villacryl H Plus V4 powder 50kg	I	5		
V100V4P18	Villacryl H Plus V4 powder 30g	I	5		
V100V4Z12	Villacryl H Plus V4 powder 750g+ liquid 400ml	I	5		
V100V4Z13	Villacryl H Plus V4 powder 300g+ liquid 150ml	I	5		
V100L05	Villacryl H Plus liquid 1l	I	5		
V100L06	Villacryl H Plus liquid 400ml	I	5		
V100L07	Villacryl H Plus liquid 150ml	I	5		
V100L08	Villacryl H Plus liquid 12ml	I	5		
Intended use of the product:	Heat curing acrylic resin for denture bases				
* Classification rules	ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745				
Basic UDI-DI	590160212DBQ3				
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX,. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>					
Harmonized Standards applied:	EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-18:2009				
Technical standards ref:	EN ISO 20795-1:2013 - Dentistry - Base polymers - Part 1 - Denture base polymers				
EC certificate:	N/A				

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Place: Warszawa

Date of issue: 2021-05-25

Signature: _____

Andrzej Cegliński

Quality Assurance and Regulatory Compliance Manager

EVERALL7 Sp. z o.o.

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NIP 521-01-24-886, Regon 002028511

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**DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/74
No: KW-AK04/V140/EN**

Manufacturer:		Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (SRN): -		
Authorized EU-representative:		Name of the site, Address of the site – N/A		
PRODUCT CODE / CATALOGUE NUMBER	NAME	Class	Rule*	
V140RZ03	Villacryl IT pink powder 750 g + liquid 200 ml	I	5	
V140RZ06	Villacryl IT pink powder 21 g + liquid 6 ml	I	5	
V140ZZ04	Villacryl IT green powder 750 g + liquid 200 ml	I	5	
V140ZZ07	Villacryl IT green powder 21 g + liquid 6 ml	I	5	
V140ZP02	Villacryl IT green powder 750 g	I	5	
V140RP05	Villacryl IT pink powder 750 g	I	5	
V140ZL01	Villacryl IT liquid 200 ml	I	5	
Intended use of the product:		Acrylic resin for individual trays		
* Classification rules		ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745		
Basic UDI-DI		590160212ITRN		
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX,. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.				
Harmonized Standards applied:		EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-18:2009		
Technical standards ref:		FACTORY STANDARD ZN-05/10 Villacryl IT - Acrylic resin for individual trays		
EC certificate:		N/A		

Place: Warszawa

Date of issue: 2021-05-25

Signature: _____

Andrzej Cegliński

Quality Assurance and Rregulatory Compliance Manager

EVERALL7 Sp. z o.o.

ul. Augustówka 14, 02-981 Warszawa

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NIP 521-01-24-886, Regon 002028511

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**DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/74
No: KW-AK09/V110/EN**

Manufacturer:		Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (SRN): -	
Authorized EU-representative:		Name of the site, Address of the site – N/A	
PRODUCT CODE / CATALOGUE NUMBER	NAME	Class	Rule*
V1100Z01	Villacryl H Rapid color 0 750 g powder + 400 ml liquid	I	5
V1100P13	Villacryl H Rapid color 0 powder 750 g	I	5
V1100P17	Villacryl H Rapid color 0 powder 2 kg	I	5
V1100P21	Villacryl H Rapid color 0 powder 4 kg	I	5
V110V2Z05	Villacryl H Rapid color V2 750 g powder + 400 ml liquid	I	5
V110V2P14	Villacryl H Rapid color V2 powder 750 g	I	5
V110V2P18	Villacryl H Rapid color V2 powder 2 kg	I	5
V110V2P22	Villacryl H Rapid color V2 powder 4 kg	I	5
V110V3P15	Villacryl H Rapid color V3 powder 750 g	I	5
V110V3P19	Villacryl H Rapid color V3 powder 2 kg	I	5
V110V3P23	Villacryl H Rapid color V3 powder 4 kg	I	5
V110V4Z07	Villacryl H Rapid color V4 750 g powder + 400 ml liquid	I	5
V110V4P11	Villacryl H Rapid color V4 powder 750 g	I	5
V110V4P08	Villacryl H Rapid color V4 powder 2 kg	I	5
V110V4P09	Villacryl H Rapid color V4 powder 4 kg	I	5
V110T4P16	Villacryl H Rapid color T4 powder 750 g	I	5
V110T4P20	Villacryl H Rapid color T4 powder 2 kg	I	5
V110T4P24	Villacryl H Rapid color T4 powder 4 kg	I	5
V110L04	Villacryl H Rapid Liquid 400 ml	I	5
V110L02	Villacryl H Rapid Liquid 1 l	I	5
Intended use of the product: Fast heat curing acrylic resin for denture bases			
* Classification rules		ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745	
Basic UDI-DI		590160212DBQ3	
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION 2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX,. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.			
Harmonized Standards applied:		EN ISO 13485 :2016 EN ISO 14971 :2012 EN 1041:2013 EN ISO 15223-1:2016 EN 1641:2009 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-18:2009	
Technical standards ref:		EN ISO 20795-1:2013 - Dentistry - Base polymers - Part 1 - Denture base polymers	
EC certificate:		N/A	

Place: Warszawa
Date of issue: 2021-05-25

Signature: _____
Andrzej Cegliński
Quality Assurance and Regulatory Compliance Manager

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