

The management system of

Everall7 Sp. z o.o.

ul. Augustówka 14, 02-981 Warszawa, Poland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

For the following products

Villacryl STC Hot - Heat-curing acrylic resin for crowns and bridges veneering
Villacryl Opaker - Universal metal masking material
Prowident - Temporary filling material

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 24 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 21 June 2001

Certification is based on reports numbered PL/WAW PL00098a

Authorised by



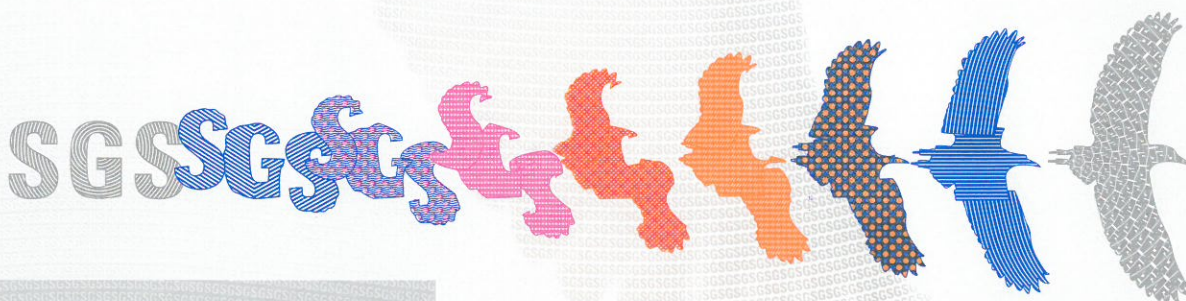
Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Rev. 002

CE DECLARATION OF CONFORMITY

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

Manufacturer:	Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (DUNS) - N/A		
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	Ila	Rule 8
V210A2Z02	Villacryl STC Hot color A2 powder 80g + liquid 40ml	Ila	Rule 8
V210A3Z04	Villacryl STC Hot color A3.5 powder 80g + liquid 40ml	Ila	Rule 8
V210A3Z03	Villacryl STC Hot color A3 powder 80g + liquid 40ml	Ila	Rule 8
V210A4Z04	Villacryl STC Hot color A4 powder 80g + liquid 40ml	Ila	Rule 8
V210B1Z06	Villacryl STC Hot color B1 powder 80g + liquid 40ml	Ila	Rule 8
V210B2Z07	Villacryl STC Hot color B2 powder 80g + liquid 40ml	Ila	Rule 8
V210C2Z08	Villacryl STC Hot color C2 powder 80g + liquid 40ml	Ila	Rule 8
V210C4Z09	Villacryl STC Hot color C4 powder 80g + liquid 40ml	Ila	Rule 8
V210D2Z12	Villacryl STC Hot color D2 4 powder 80g + liquid 40ml	Ila	Rule 8
V210Z11	Villacryl STC Hot ZESTAW	Ila	Rule 8
V210L01	Villacryl STC Hot liquid 40 ml	Ila	Rule 8
V210L02	Villacryl STC Hot liquid 200 ml	Ila	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

EVERALL7 Sp. z o.o.
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