

**DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC
No. KW-AK12/V210Z10/2021/E**

Manufacturer:	<p>Everall7 Sp. z o.o. ul. Augustówka 14 02-981 Warsaw (Poland) Single registration number (DUNS) - PL-MF-000018646</p>		
Authorized EU-representative:	Name of the site, Address of the site – N/A		
PRODUCT CODE / CATALOGUE NUMBER	NAME	Classification	Rule*
V210Z10	Villacryl Opaker 4x7g powder + 2x12ml liquid + 12ml primer	Ila	Rule 8
V210Z12	Villacryl Opaker 2x7g powder + 12ml liquid + 12ml primer	Ila	Rule 8
Purpose of the product:	Universal metal masking material		
GMDN Code :	38781 - Crown/bridge material, polymer based		
Classification rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC		
<p>WE HEREWITH DECLARES THAT THE ABOVE MENTIONED PRODUCTS:</p> <ul style="list-style-type: none"> - 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 DEECLARATION OF CONFORMITY. 			
Harmonized Standards applied:	<p>EN ISO 13485 :2016 EN ISO 14971 :2019 EN ISO 20417:2021 EN ISO 15223-1:2021 EN 1641:2009 EN ISO 10993-1: 2020 EN ISO 10993-5:2009 EN ISO10993-10:2013 EN ISO 10993-18:2020</p>		
Technical standards ref.:	ISO 10477:2018 - Dentistry - Polymer-based crown and veneering materials		
EC certificate :	<p>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</p>		

Place: Warsaw
Date: 2021-04-28

Signature: _____
Andrzej Cegliński

Quality Assurance and Rfegulatory Compliance Manager