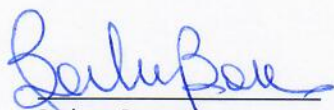


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	NAME	PACKAGING	CLASSIFICATION	RULE
C700201	Acrytemp	1x50 ml (76 g) cartridge (Base + Catalyst) + 15 Mixing Tips 4:1 - A1	Class IIa	Rule 7 Rule 8.1
C700200	Acrytemp	1x50 ml (76 g) cartridge (Base + Catalyst) + 15 Mixing Tips 4:1 - A2	Class IIa	Rule 7 Rule 8.1
C700215	Acrytemp	1x50 ml (76 g) cartridge (Base + Catalyst) + 15 Mixing Tips 4:1 - A3	Class IIa	Rule 7 Rule 8.1
C700205	Acrytemp	1x50 ml (76 g) cartridge (Base + Catalyst) + 15 Mixing Tips 4:1 - A3.5	Class IIa	Rule 7 Rule 8.1
C700211	Acrytemp	1x50 ml (76 g) cartridge (Base + Catalyst) + 15 Mixing Tips 4:1 - B1	Class IIa	Rule 7 Rule 8.1
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use :	Acrylic resins for dental use			
<p>WE HEREWIT DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEXES I, II (excluding section 4), X, XII. 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 ISO 10993-1: 2009 EN ISO 7405:2008+A1:2013 EN 1041:2008+A1: 2013 ISO 15223-1: 2016 DIN EN 1641:2010			
Technical standards ref.:	/			
EC certificate :	According to annex II section 3 of the Directive 93/42/EEC No. G1 053618 0027 Rev. 01 valid until 2024/03/19 TUV SUD PS (0123), Ridlerstrasse 65, 80339 Muchen - Germany			

Zhermack S.p.A.
Via Bovazecchino, 100
45021 – Badia Polesine (Ro)

Badia Polesine, 23.04.2021



Barbara Baruzzo
QA/RA Manager

