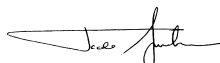


## DECLARATION OF CONFORMITY

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY		
Product:	<b>CODE</b>	<b>NAME</b>	<b>DESCRIPTION</b>
	C700200	Acrytemp	76gr(50ml)cartuccia/cartridge+15 Mixing Tips - A2
	C700215	Acrytemp	76gr(50ml)cartuccia/cartridge+15 Mixing Tips - A3
	C700205	Acrytemp	76gr(50ml)cartuccia/cartridge+15 Mixing Tips - A3.5
	C710080	Elite Hard Relining	1 barattolo polvere 60 g+1 flacone liquido 40 ml+1 flaconcino di conditioner 10 ml/1 powder tub 60 g+1 liquid bottle 40 ml+1 conditioner bottle
Intended use :	Acrylic resins for dental use		
Classification :	CLASS IIa, RULE 5 ANNEX IX MDD 93/42/CE amended by MDD 2007/47/CE		
WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/CEE AMENDED BY DIR. 2007/47/CE FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.			
Standard applied :	UNI EN ISO 13485 :2012 UNI CEI EN ISO 14971:2012 UNI EN ISO 10993-1:2010 UNI EN ISO 10993-5 :2009 UNI EN 1641:2010 UNI EN 1041:2013 UNI EN 980:2009 UNI EN ISO 14155:2011 UNI CEI ISO/IEC 17050-1 : 2010		
Technical <u>standards</u> ref.:	UNI EN ISO 20795-1 : 2009		
EC certificate :	In according to annex II section 3 of the Directive 93/42/EEC <b><u>N° G1 15 04 53618 020 valid until 2020/05/05</u></b> TUV SUD PS (0123), Ridlerstrasse 65, 80339 Munchen - Germany		
Validity of Declaration of conformity:	Valid until: <b><u>05/05/2020</u></b>		
Start of CE marking:	09/03/2000		

Badia Polesine, 21/05/2015

Paolo Ambrosini



General Manager  
Zhermack SpA

REV	DATA	DESCRIZIONE
1	16/09/11	Nuova dichiarazione specifica per Acrytemp e Hard Relining (precedentemente erano insieme alle altre resine acriliche di classe IIa)
2	23/04/2012	Aggiornamento firma, aggiunta campo validità dichiaraz., aggiornamento norme
3	26/02/2014	Aggiornamento normative e scadenza dichiarazione
4	10/06/2014	Correzione nomi e descrizione prodotti
5	21/05/2015	Modifica certificato

Zhermack S.p.A.

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M. RO 001381 - Isc. Reg. A.E.E. IT07111000002  
Cap. Soc. € 1.032.000,00