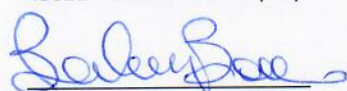


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	NAME	PACKAGING	CLASSIFICATION	RULE
C206020	ELITE P&P LIGHT BODY NORMAL SET	2x60 ml tubes (Base + Catalyst)	Class I	Rule 5
C206010	ELITE P&P LIGHT BODY NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 6 mixing tips	Class I	Rule 5
C206011	ELITE P&P LIGHT BODY FAST SET	2x50 ml cartridges (Base + Catalyst) + 6 mixing tips	Class I	Rule 5
C206021	ELITE P&P REGULAR BODY NORMAL SET	2x60 ml tubes (Base + Catalyst)	Class I	Rule 5
C206012	ELITE P&P REGULAR BODY NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 6 mixing tips	Class I	Rule 5
C206000	ELITE P&P PUTTY SOFT NORMAL SET	2x250 ml tubs (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
H100865	ELITE P&P PUTTY SOFT NORMAL SET	1x100 ml tub Base	Class I	Rule 5
H100866	ELITE P&P PUTTY SOFT NORMAL SET	1x100 ml tub Catalyst	Class I	Rule 5
C206001	ELITE P&P PUTTY SOFT FAST SET	2x250 ml tubs (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
C206102	ELITE P&P INTRO KIT	2x250 ml ELITE P&P PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 2 measuring spoons + 2x50 ml ELITE P&P LIGHT BODY NORMAL SET cartridges (Base + Catalyst) + 6 mixing tips + 2 oral tips + 1 dispenser D2	Class I	Rule 5
C206110	ELITE P&P TRIAL KIT	2x100 ml ELITE P&P PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 2 measuring spoons + 2x60 ml ELITE P&P LIGHT BODY NORMAL SET tubes (Base + Catalyst)	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use:	Addition silicone impression material			
WE HEREWITH 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, VII, X, XII. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.				
Standards applied:	EN ISO 13485: 2016 EN ISO 14971: 2012 ISO 10993-1: 2009 EN 1041: 2008+A1: 2013 ISO 15223-1: 2016			
Technical standards ref.:	ISO 4823: 2015			
EC certificate:	Not applicable			

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



Barbara Baruzzo
QA/RA Manager



Zhermack S.p.A.

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Badia Polesine, 23.04.2021