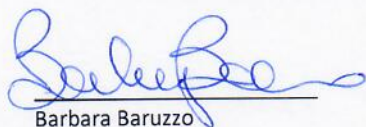


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	NAME	PACKAGING	CLASSIFICATION	RULE
C100600	ZETAPLUS	900 ml tub + measuring spoon	Class I	Rule 5
C100312	ZETAPLUS	1800 ml tub + measuring spoon	Class I	Rule 5
C100468	ZETAPLUS	10 Kg drum + measuring spoon	Class I	Rule 5
C100100	ZETAPLUS	576 ml tub + measuring spoon	Class I	Rule 5
C100610	ZETAPLUS SOFT	900 ml tub + measuring spoon	Class I	Rule 5
C100660	ORANWASH L	140 ml tube	Class I	Rule 5
C100650	ORANWASH VL	140 ml tube	Class I	Rule 5
C100700	INDURENT GEL	60 ml tube	Class I	Rule 5
C100720	ZETAPLUS L MINI KIT	1 Indurent Gel 60 ml + 1 Oranwash L 40 ml + 1 Zetaplus 200 ml + 1 mixing pad + measuring spoon	Class I	Rule 5
C100730	ZETAPLUS L INTRO KIT	1 Indurent Gel 60 ml + 1 Oranwash L 140 ml + 1 Zetaplus 900 ml + 1 mixing pad + measuring spoon	Class I	Rule 5
C100740	ZETAPLUS VL INTRO KIT	1 Indurent Gel 60 ml + 1 Oranwash VL 140 ml + 1 Zetaplus Soft 900 ml + 1 mixing pad + measuring spoon	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use:	C-Silicone dental 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 EN 62366: 2008			
Technical standards ref.:	ISO 4823: 2015			
EC certificate:	Not applicable			

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

Badia Polesine, 23.04.2021



Barbara Baruzzo
QA/RA Manager

