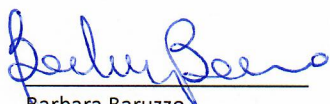


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	BRAND NAME	PACKAGING	Classification	Rule
C100600	ZETAPLUS	900 ml barattolo/tub	Class I	Rule 5
C100312	ZETAPLUS	1800 ml barattolo/tub	Class I	Rule 5
C100468	ZETAPLUS	10 Kg secchiello/drum	Class I	Rule 5
C100610	ZETAPLUS SOFT	900 ml barattolo/tub	Class I	Rule 5
C100660	ORANWASH L	140 ml tubo/tube	Class I	Rule 5
C100650	ORANWASH VL	140 ml tubo/tube	Class I	Rule 5
C100670	THIXOFLEX M	140 ml tubo/tube	Class I	Rule 5
C100550	ORTHOGUM	1500 ml barattolo/tub	Class I	Rule 5
C100700	INDURENT GEL	60 ml tubo/tube	Class I	Rule 5
C100800	ZETAFLOW PUTTY	900 ml barattolo/tub	Class I	Rule 5
C100810	ZETAFLOW LIGHT	140 ml tubo/tube	Class I	Rule 5
C100890	ZETAFLOW CATALYST	60 ml tubo/tube	Class I	Rule 5
C100720	ZETAPLUS L TRIAL KIT	1 Indurent Gel 60 ml + 1 Oranwash L 40 ml + 1 Zetaplus 200 ml + 1 Mixing pad	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	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	Class I	Rule 5
C100850	ZETAFLOW INTRO KIT	1 Zetaflow Catalyst 60 ml + 1 Zetaflow Light 140 ml + 1 Zetaflow Putty 900 ml + 1 Mixing pad	Class I	Rule 5
C100859	ZETAFLOW TRIAL KIT	1 Zetaflow Catalyst 60 ml + 1 Zetaflow Light 40 ml + 1 Zetaflow Putty 200 ml + 1 Mixing pad	Class I	Rule 5
ACCESSORIES				
C207201	MIXING PAD	20 pcs/pack	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
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 DEECLARATION OF CONFORMITY.				
Harmonized Standards applied:	UNI EN ISO 13485: 2016 UNI CEI EN ISO 14971: 2012 UNI EN ISO 10993-1: 2010 UNI CEI EN 1041: 2013 ISO 15223-1: 2016			
Technical standards ref.:	UNI EN ISO 4823: 2015			
EC certificate :	Not applicable			

Zhermack S.p.A.
Via Bovazecchino, 100
450021 – Badia Polesine (Ro)



Barbara Baruzzo
QA/RA Manager

Badia Polesine, 22.10.2018