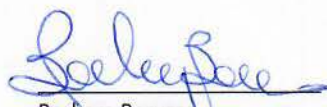


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

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
C700025	UNIVERSAL TRAY ADHESIVE	10 ml bottle	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use :	Adhesive for silicones for dental impression			
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.				
Harmonized Standards applied:	UNI EN ISO 13485: 2016 UNI CEI EN ISO 14971: 2012 UNI CEI EN 1041: 2013 ISO 15223-1: 2016			
Technical standards ref.:	/			
EC certificate :	Not applicable			

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

Badia Polesine, 23.07.2019



Barbara Baruzzo
QA/RA Manager

