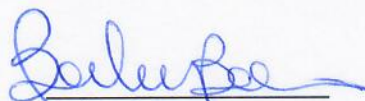


**DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC**

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>	<b>PACKAGING</b>	<b>CLASSIFICATION</b>	<b>RULE</b>
C401610	ELITE GLASS	2X50 ml cartridges (Base + Catalyst) + 6 mixing tips	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			
<p>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.</p>				
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)

Badia Polesine, 23.04.2021



Barbara Baruzzo  
QA/RA Manager

