

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
C200750	COLORBITE D	2x50ml cartucce/cartridges + 12 medium/green mixing tips	Class I	Rule 5
C203236	COLORBITE D	1x50ml cartuccia/cartridge	Class I	Rule 5
C200760	COLORBITE ROCK	2x50ml cartucce/cartridges + 12 medium/green mixing tips	Class I	Rule 5
C200761	COLORBITE ROCK	1x50ml cartuccia/cartridge	Class I	Rule 5
C200726	OCCLUFAST ROCK	2x50ml cartucce/cartridges + 12 medium/green mixing tips	Class I	Rule 5
C200727	OCCLUFAST ROCK	2x50ml cartucce/cartridges + 12 medium/green mixing tips	Class I	Rule 5
C203220	OCCLUFAST ROCK	1x50ml cartuccia/cartridge	Class I	Rule 5
C200800	OCCLUFAST CAD	2x50ml cartucce/cartridges + 12 medium/green mixing tips	Class I	Rule 5
C200790	OCCLUFAST+	1x50ml cartucce/ cartridges + 6 small/yellow mixing tips	Class I	Rule 5
C200791	OCCLUFAST+	2x50ml cartucce/ cartridges + 12 small/yellow mixing tips	Class I	Rule 5
C200792	OCCLUFAST+	8x50ml cartucce/ cartridges	Class I	Rule 5
C200780	OCCLUFAST+ COLOR	1x50ml cartucce/ cartridges + 6 small/yellow mixing tips	Class I	Rule 5
C200781	OCCLUFAST+ COLOR	2x50ml cartucce/ cartridges + 12 small/yellow mixing tips	Class I	Rule 5
C200782	OCCLUFAST+ COLOR	8x50ml cartucce/ cartridges	Class I	Rule 5
ACCESSORIES				
C202080	MIXING TIPS MEDIUM/GREEN	48 pcs/pack	Class I	Rule 5
C202070	MIXING TIPS SMALL/YELLOW	48 pcs/pack	Class I	Rule 5
C202095	BITE ORAL TIPS	48 pcs/pack	Class I	Rule 5
C202100	DISPENSER D2	1 pc/pack	Class I	Rule 1
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use :	Vinylpolysiloxane bite registration 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 DEDECLARATION OF CONFORMITY.</p>				

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.:	/
EC certificate :	Not applicable

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Badia Polesine, 14.06.2019


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