

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
C203000	ELITE HD+ PUTTY SOFT NORMAL SET	2x250 ml tubs (Base + Catalyst)	Class I	Rule 5
C203002	ELITE HD+ PUTTY SOFT NORMAL SET	2X450 ml tubs (Base + Catalyst)	Class I	Rule 5
C203013	ELITE HD+ PUTTY SOFT NORMAL SET	1x100 ml tub Base	Class I	Rule 5
C203014	ELITE HD+ PUTTY SOFT NORMAL SET	1x100 ml tub Catalyst	Class I	Rule 5
H100011	ELITE HD+ PUTTY SOFT NORMAL SET	1x20 ml tub Base	Class I	Rule 5
H100012	ELITE HD+ PUTTY SOFT NORMAL SET	1x20 ml tub Catalyst	Class I	Rule 5
C203092	ELITE HD+ PUTTY SOFT NORMAL SET	48x100 ml tubs (Base + Catalyst)	Class I	Rule 5
C203010	ELITE HD+ PUTTY SOFT FAST SET	2x250 ml tubs (Base + Catalyst)	Class I	Rule 5
C203012	ELITE HD+ PUTTY SOFT FAST SET	2X450 ml tubs (Base + Catalyst)	Class I	Rule 5
H100017	ELITE HD+ PUTTY SOFT FAST SET	1x20 ml tub Base	Class I	Rule 5
H100018	ELITE HD+ PUTTY SOFT FAST SET	1x20 ml tub Catalyst	Class I	Rule 5
C203091	ELITE HD+ PUTTY SOFT FAST SET	11X450 ml tubs (Base + Catalyst)	Class I	Rule 5
C203205	ELITE HD+ LIGHT BODY NORMAL SET	1x50 ml cartridge (Base + Catalyst)	Class I	Rule 5
C203030	ELITE HD+ LIGHT BODY NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips small/yellow	Class I	Rule 5
C203035	ELITE HD+ LIGHT BODY NORMAL SET	2x90 ml tubes (Base + Catalyst)	Class I	Rule 5
C203210	ELITE HD+ LIGHT BODY FAST SET	1x50 ml cartridge (Base + Catalyst)	Class I	Rule 5
C203040	ELITE HD+ LIGHT BODY FAST SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips small/yellow	Class I	Rule 5
C203090	ELITE HD+ LIGHT BODY FAST SET	150x50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C203050	ELITE HD+ SUPER LIGHT BODY FAST SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips small/yellow	Class I	Rule 5
H100420	ELITE HD+ REGULAR BODY NORMAL SET	1x50 ml cartridge (Base + Catalyst)	Class I	Rule 5
C203020	ELITE HD+ REGULAR BODY NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips small/yellow	Class I	Rule 5
C203025	ELITE HD+ REGULAR BODY NORMAL SET	2x90 ml tubes (Base + Catalyst)	Class I	Rule 5

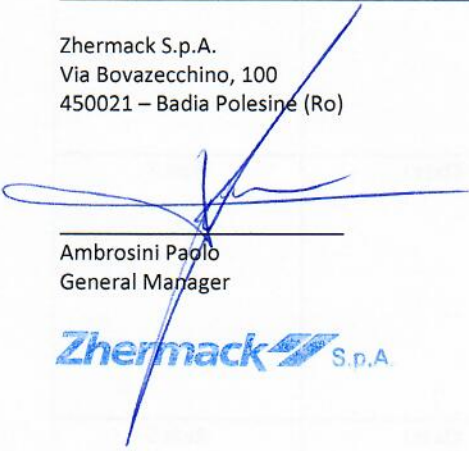


C202032	ELITE HD+ TRAY MATERIAL FAST SET	2x50 ml cartridges (Base + Catalyst) + 6 mixing tips medium/green	Class I	Rule 5
C202020	ELITE HD+ MONOPHASE NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips small/yellow	Class I	Rule 5
C202320	ELITE HD+ MAXI TRAY MATERIAL FAST SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C202330	ELITE HD+ MAXI TRAY MATERIAL FAST SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C202300	ELITE HD+ MAXI MONOPHASE NORMAL SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C202310	ELITE HD+ MAXI MONOPHASE NORMAL SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C202340	ELITE HD+ MAXI PUTTY SOFT NORMAL SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C202350	ELITE HD+ MAXI PUTTY SOFT NORMAL SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C202360	ELITE HD+ MAXI PUTTY SOFT FAST SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C202370	ELITE HD+ MAXI PUTTY SOFT FAST SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C203100	ELITE HD+ INTRO KIT	2x250 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 1X50 ml ELITE HD+ REGULAR BODY NORMAL SET cartridge (Base + Catalyst) + 1X50 ml ELITE HD+ LIGHT BODY NORMAL SET cartridge (Base + Catalyst) + 1 Dispenser D2 + 12 mixing tips small/yellow + 6 oral tips yellow	Class I	Rule 5
C203122	ELITE HD+ SPECIAL PACK	2x250 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 4X50 ml ELITE HD+ LIGHT BODY NORMAL SET cartridges (Base + Catalyst) + 1 Dispenser D2 + 24 mixing tips small/yellow + 24 small/yellow oral tips	Class I	Rule 5
C207081	MINI KIT ELITE HD+ NORMAL SET	2x20 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 1X50 ml ELITE HD+ LIGHT BODY NORMAL SET cartridge	Class I	Rule 5

		(Base + Catalyst) + 1 mixing tip small/yellow + 1 oral tip yellow		
C207082	MINI KIT ELITE HD+ FAST SET	2x20 ml ELITE HD+ PUTTY SOFT FAST SET tubs (Base + Catalyst) + 1X50 ml ELITE HD+ LIGHT BODY FAST SET cartridge (Base + Catalyst) + 1 mixing tip small/yellow + 1 oral tip yellow	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
ACCESSORIES				
C203233	MIXING TIPS EXTRA SMALL/BLUE	48 pcs pack	Class I	Rule 5
C202070	MIXING TIPS SMALL/YELLOW	48 pcs pack	Class I	Rule 5
C202090	ORAL TIPS YELLOW	48 pcs pack	Class I	Rule 5
C202080	MIXING TIPS MEDIUM/GREEN	48 pcs pack	Class I	Rule 5
C205530	DYNAMIC STATIC MIXING TIPS	50 pcs pack	Class I	Rule 1
C205540	MIXING TIPS LOCKERS	2 pcs pack	Class I	Rule 1
C202100	DISPENSER D2	1 pc pack	Class I	Rule 1
C207202	MIXING PAD	12 pcs pack	Class I	Rule 1
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
<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 EN ISO 10993-5:2009 UNI EN 1641:2010 UNI CEI EN 1041:2013 ISO 15223-1:2016			
Technical standards ref.:	ISO 4823:2015			
EC certificate :	Not applicable			

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Badia Polesine, 20.07.2018


 Ambrosini Paolo
 General Manager

