

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	NAME	PACKAGING	CLASSIFICATION	RULE
C203000	ELITE HD+ PUTTY SOFT NORMAL SET	2x250 ml tubs (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
C203002	ELITE HD+ PUTTY SOFT NORMAL SET	4x450 ml tubs (Base + Catalyst) + 2 measuring spoons	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	96x100 ml tubs (Base + Catalyst) + 96 measuring spoons	Class I	Rule 5
C203010	ELITE HD+ PUTTY SOFT FAST SET	2x250 ml tubs (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
C203012	ELITE HD+ PUTTY SOFT FAST SET	4x450 ml tubs (Base + Catalyst) + 2 measuring spoons	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	22x450 ml tubs (Base + Catalyst) + 22 measuring spoons	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	Class I	Rule 5
C203035	ELITE HD+ LIGHT BODY NORMAL SET	2x90 ml tubes (Base + Catalyst)	Class I	Rule 5
C203040	ELITE HD+ LIGHT BODY FAST SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	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	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	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	Class I	Rule 5
C202020	ELITE HD+ MONOPHASE NORMAL SET	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C202320	ELITE HD+ MAXI TRAY MATERIAL FAST SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tip lockers	Class I	Rule 5
C202330	ELITE HD+ MAXI TRAY MATERIAL FAST SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tip lockers	Class I	Rule 5
C202300	ELITE HD+ MAXI MONOPHASE NORMAL SET	2x380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tip lockers	Class I	Rule 5

C202310	ELITE HD+ MAXI MONOPHASE NORMAL SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tip 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 tip lockers	Class I	Rule 5
C202350	ELITE HD+ MAXI PUTTY SOFT NORMAL SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tip 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 tip lockers	Class I	Rule 5
C202370	ELITE HD+ MAXI PUTTY SOFT FAST SET	6x380 ml cartridges (Base + Catalyst) + 2 mixing tip lockers	Class I	Rule 5
C203100	ELITE HD+ INTRO KIT	2x250 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 2 measuring spoons + 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 + 6 oral tips	Class I	Rule 5
C203122	ELITE HD+ SPECIAL PACK	4x250 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 4 measuring spoons + 4x50 ml ELITE HD+ LIGHT BODY NORMAL SET cartridges (Base + Catalyst) + 1 dispenser D2 + 24 mixing tips + 24 oral tips	Class I	Rule 5
C203127	ELITE HD+ SPECIAL PACK	2x250 ml ELITE HD+ PUTTY SOFT NORMAL SET tubs (Base + Catalyst) + 2 measuring spoons + 2x50 ml ELITE HD+ LIGHT BODY NORMAL SET cartridges (Base + Catalyst) + 12 mixing tips + 12 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 (Base + Catalyst) + 1 mixing tip + 1 oral tip	Class I	Rule 5
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 + 1 oral tip	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			
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.				

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

