

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
C207002	HYDRORISE EXTRA LIGHT BODY NORMAL SET	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
C207003	HYDRORISE EXTRA LIGHT BODY FAST SET	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
C207008	HYDRORISE HEAVY BODY NORMAL SET	2X50 ml cartridges (Base + Catalyst) + 6 medium/green mixing tips	Class I	Rule 5
H110209	HYDRORISE HEAVY BODY FAST SET	1X50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C207009	HYDRORISE HEAVY BODY FAST SET	2X50 ml cartridges (Base + Catalyst) + 6 medium/green mixing tips	Class I	Rule 5
C207021	HYDRORISE LIGHT BODY FAST SET	1X50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C207001	HYDRORISE LIGHT BODY FAST SET	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
H110200	HYDRORISE LIGHT BODY NORMAL SET	1X50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C207000	HYDRORISE LIGHT BODY NORMAL SET	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
C207004	HYDRORISE REGULAR BODY NORMAL SET	2X50 ml cartridges (Base + Catalyst) + 12 large/pink mixing tips	Class I	Rule 5
C207005	HYDRORISE REGULAR BODY FAST SET	2X50 ml cartridges (Base + Catalyst) + 12 large/pink mixing tips	Class I	Rule 5
C207027	HYDRORISE MONOPHASE FAST SET	1X50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C207006	HYDRORISE MONOPHASE NORMAL SET	2X50 ml cartridges (Base + Catalyst) + 6 large/pink mixing tips	Class I	Rule 5
C207007	HYDRORISE MONOPHASE FAST SET	2X50 ml cartridges (Base + Catalyst) + 6 large/pink mixing tips	Class I	Rule 5
C207010	HYDRORISE PUTTY NORMAL SET	2X300 ml tub (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
C207012	HYDRORISE PUTTY NORMAL SET	2X900 ml tub (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
H100007	HYDRORISE PUTTY NORMAL SET	1X20 ml tub Base	Class I	Rule 5
H100009	HYDRORISE PUTTY NORMAL SET	1X20 ml tub Catalyst	Class I	Rule 5
C207011	HYDRORISE PUTTY FAST SET	2X300 ml tub (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
C207013	HYDRORISE PUTTY FAST SET	2X900 ml tub (Base + Catalyst) + 2 measuring spoons	Class I	Rule 5
H110212	HYDRORISE PUTTY FAST SET	1X100 ml tub Base	Class I	Rule 5
H110213	HYDRORISE PUTTY FAST SET	1X100 ml tub Catalyst	Class I	Rule 5
H100013	HYDRORISE PUTTY FAST SET	1X20 ml tub Base	Class I	Rule 5
H100014	HYDRORISE PUTTY FAST SET	1X20 ml tub Catalyst	Class I	Rule 5

C207042	HYDRORISE MAXI HEAVY BODY NORMAL SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207062	HYDRORISE MAXI HEAVY BODY NORMAL SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C207053	HYDRORISE MAXI HEAVY BODY FAST SET	1X380 ml cartridges (Base + Catalyst) + 7 dynamic-static mixing tips + 1 mixing tips lockers	Class I	Rule 5
C207043	HYDRORISE MAXI HEAVY BODY FAST SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207063	HYDRORISE MAXI HEAVY BODY FAST SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C207040	HYDRORISE MAXI MONOPHASE NORMAL SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers + 15 intraoral tips	Class I	Rule 5
C207060	HYDRORISE MAXI MONOPHASE NORMAL SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers + 45 intraoral tips	Class I	Rule 5
C207051	HYDRORISE MAXI MONOPHASE FAST SET	1X380 ml cartridges (Base + Catalyst) + 7 dynamic-static mixing tips + 1 mixing tip locker + 15 intraoral tips	Class I	Rule 5
C207041	HYDRORISE MAXI MONOPHASE FAST SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers + 15 intraoral tips	Class I	Rule 5
C207061	HYDRORISE MAXI MONOPHASE FAST SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers + 45 intraoral tips	Class I	Rule 5
C207044	HYDRORISE MAXI PUTTY NORMAL SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207064	HYDRORISE MAXI PUTTY NORMAL SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C207055	HYDRORISE MAXI PUTTY FAST SET	1X380 ml cartridges (Base + Catalyst) + 7 dynamic-static mixing tips + 1 mixing tip lockers	Class I	Rule 5
C207045	HYDRORISE MAXI PUTTY FAST SET	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207065	HYDRORISE MAXI PUTTY FAST SET	6X380 ml cartridges (Base + Catalyst) + 2 mixing tips lockers	Class I	Rule 5
C207071	HYDRORISE TRIAL KIT	2X100 ml tub (Base + Catalyst) HYDRORISE PUTTY FAST + 2 measuring spoons + 1X50 ml cartridge (Base + Catalyst) HYDRORISE LIGHT FAST + 6 small/yellow mixing tips	Class I	Rule 5
C207077	HYDRORISE TRIAL KIT	1X50 ml cartridge (Base + Catalyst) HYDRORISE HEAVY FAST + 1X50 ml cartridge (Base + Catalyst) HYDRORISE LIGHT FAST + 6 small/yellow mixing tips + 3 medium/green mixing tips	Class I	Rule 5
C207084	HYDRORISE TRIAL KIT	2X100 ml tub (Base + Catalyst) HYDRORISE PUTTY NORMAL + 2 measuring spoons + 1X50 ml cartridge (Base + Catalyst)	Class I	Rule 5

		HYDRORISE LIGHT NORMAL + 6 small/yellow mixing tips		
C207080	MINI KIT HYDRORISE NORMAL SET	2X20 ml tub (Base + Catalyst) HYDRORISE PUTTY NORMAL SET + 1X50 ml cartridge (Base + Catalyst) HYDRORISE LIGHT BODY NORMAL SET + 1 small/yellow mixing tip + 1 intraoral tip	Class I	Rule 5
C207083	MINI KIT HYDRORISE FAST SET	2X20 ml tub (Base + Catalyst) HYDRORISE PUTTY FAST SET + 1X50 ml cartridge (Base + Catalyst) HYDRORISE LIGHT BODY FAST SET + 1 small/yellow mixing tip + 1 intraoral tip	Class I	Rule 5
C207090	HYDRORISE IMPLANT HEAVY BODY	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207092	HYDRORISE IMPLANT MEDIUM BODY	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207091	HYDRORISE IMPLANT LIGHT BODY	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
C207095	HYDRORISE IMPLANT KIT HEAVY/LIGHT	1X380 ml cartridge HYDRORISE IMPLANT HEAVY BODY (Base + Catalyst) + 6 dynamic-static mixing tips + 1 mixing tips locker + 1X50 ml cartridge HYDRORISE IMPLANT LIGHT BODY (Base + Catalyst) + 6 small/yellow mixing tips	Class I	Rule 5
C207096	HYDRORISE IMPLANT MEDIUM BODY	1X380 ml cartridge (Base + Catalyst) + 6 dynamic-static mixing tips + 1 mixing tips locker	Class I	Rule 5
C207120	HYDRORISE IMPLANT HEAVY BODY	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207121	HYDRORISE IMPLANT LIGHT BODY	2X50 ml cartridges (Base + Catalyst) + 12 small/yellow mixing tips	Class I	Rule 5
C207122	HYDRORISE IMPLANT MEDIUM BODY	2X380 ml cartridges (Base + Catalyst) + 15 dynamic-static mixing tips + 2 mixing tips lockers	Class I	Rule 5
C207125	HYDRORISE IMPLANT KIT HEAVY/LIGHT	1X380 ml cartridge HYDRORISE IMPLANT HEAVY BODY (Base + Catalyst) + 6 dynamic-static mixing tips + 1 mixing tips locker + 1X50 ml cartridge HYDRORISE IMPLANT LIGHT BODY (Base + Catalyst) + 6 small/yellow mixing tips	Class I	Rule 5
C207126	HYDRORISE IMPLANT MEDIUM BODY	1X380 ml cartridge (Base + Catalyst) + 6 dynamic-static mixing tips + 1 mixing tips locker	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
C205500	MIXING TIPS LARGE/PINK	48 pcs/pack	Class I	Rule 5
C202090	ORAL TIPS YELLOW	48 pcs/pack	Class I	Rule 5
C202100	DISPENSER D2	1 pc/pack	Class I	Rule 1
C205530	DYNAMIC-STATIC MIXING TIPS	50 pcs/pack	Class I	Rule 1
C205540	MIXING TIP LOCKERS	2 pcs/pack	Class I	Rule 1

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 DEDECLARATION OF CONFORMITY.	
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.:	UNI EN ISO 4823: 2015
EC certificate :	Not applicable

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Badia Polesine, 04.06.2019



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