

To whom it may concern
Non Medical Device List

I undersigned Massimo Rossi, R&D Director at Zhermack S.p.A., hereby confirm that the Zhermack products listed in the below Table are **NOT** classified as Medical Devices according to the provisions of Regulation (EU) 2017/745.

Product code	Product name	Product group	Applied standard(s)
C207200	SPATULA FOR SILICONES	Accessories - A-Silicones and C-Silicones	/
C207201	MIXING PAD	Accessories - C-Silicones	/
C202087	MIXING TIPS	Accessories - A-Silicone	/
C300960	LONG LIFE BAG	Accessories - Alginates	/
C300990	FLUORESCENT ALGinate SPATULAS	Accessories - Alginates	/
C300991	GREEN SPATULA	Accessories - Stones	/
C300992	RUBBER BOWL	Accessories - Alginates	/
C400435	ALGITRAY	Preliminary impression - Alginates	Reg. EU 2004/648
C400441	GYPSTRAY	Stone models	Reg. EU 2004/648
C400700	PLATINUM 95	Masks - A-Silicones	/
C400710	PLATINUM 95	Masks - A-Silicones	/
C400720	PLATINUM 95	Masks - A-Silicones	/
C400723	PLATINUM 85	Masks - A-Silicones	/
C400725	PLATINUM 85	Masks - A-Silicones	/
C400727	PLATINUM 85	Masks - A-Silicones	/
C400729	PLATINUM 85	Masks - A-Silicones	/
C400731	PLATINUM 95	Masks - A-Silicones	/
C400741	PLATINUM 75 CAD	Masks - A-Silicones	/
C400750	PLATINUM 85 TOUCH	Masks - A-Silicones	/
C400751	PLATINUM 85 TOUCH	Masks - A-Silicones	/
C400790	ZETALABOR	Masks - C-Silicones	/
C400791	ZETALABOR	Masks - C-Silicones	/
C400798	ZETALABOR	Masks - C-Silicones	/
C400804	ZETALABOR	Masks - C-Silicones	/
C400811	ZETALABOR	Masks - C-Silicones	/

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C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

Product code	Product name	Product group	Applied standard(s)
C400812	ZETALABOR	Masks - C-Silicones	/
C400818	TITANIUM	Masks - C-Silicones	/
C400605	TITANIUM	Masks - C-Silicones	/
C400611	TITANIUM	Masks - C-Silicones	/
C100900	INDURENT LAB	Masks - C-Silicones	/
C400820	ELITE DOUBLE 8	Duplication - A-Silicones	ISO 14356
C400821	ELITE DOUBLE 22	Duplication - A-Silicones	ISO 14356
C400823	ELITE DOUBLE 22 FAST	Duplication - A-Silicones	ISO 14356
C400825	ELITE DOUBLE 16 FAST	Duplication - A-Silicones	ISO 14356
C400830	ELITE DOUBLE 8	Duplication - A-Silicones	ISO 14356
C400831	ELITE DOUBLE 16 FAST	Duplication - A-Silicones	ISO 14356
C400832	ELITE DOUBLE 22	Duplication - A-Silicones	ISO 14356
C400833	ELITE DOUBLE 32	Duplication - A-Silicones	ISO 14356
C400834	ELITE DOUBLE 22 FAST	Duplication - A-Silicones	ISO 14356
C400836	ELITE DOUBLE 32 FAST	Duplication - A-Silicones	ISO 14356
C400840	ELITE DOUBLE 22	Duplication - A-Silicones	ISO 14356
C400841	ELITE DOUBLE 32	Duplication - A-Silicones	ISO 14356
C400842	ELITE DOUBLE 22 FAST	Duplication - A-Silicones	ISO 14356
C400843	ELITE DOUBLE 32 FAST	Duplication - A-Silicones	ISO 14356
C400847	ELITE DOUBLE 16 FAST	Duplication - A-Silicones	ISO 14356
C400849	ELITE DOUBLE 22 EXTRA FAST	Duplication - A-Silicones	ISO 14356
C400888	GINGIFAST SEPARATOR	Gingival reproduction - A-Silicones	/
C401500	GINGIFAST ELASTIC	Gingival reproduction - A-Silicones	/
C401520	GINGIFAST RIGID	Gingival reproduction - A-Silicones	/
C203227	GINGIFAST CAD ELASTIC	Gingival reproduction - A-Silicones	/
C203232	GINGIFAST CAD RIGID	Gingival reproduction - A-Silicones	/
C401600	ELITE TRANSPARENT	Masks - A-Silicones	/
C410000	ELITE ROCK WHITE	Stone models	ISO 6873
C410010	ELITE ROCK SILVER GREY	Stone models	ISO 6873
C410020	ELITE ROCK CREAM	Stone models	ISO 6873
C410030	ELITE ROCK SANDY BROWN	Stone models	ISO 6873
C410032	ELITE ROCK SANDY BROWN	Stone models	ISO 6873

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Product code	Product name	Product group	Applied standard(s)
C410033	ELITE ROCK SANDY BROWN	Stone models	ISO 6873
C410043	ELITE STONE AQUA GREEN	Stone models	ISO 6873
C410048	ELITE STONE PINK	Stone models	ISO 6873
C410050	ELITE STONE NAVY BLUE	Stone models	ISO 6873
C410040	ELITE STONE SANDY BROWN	Stone models	ISO 6873
C410063	ELITE MODEL FAST WHITE	Stone models	ISO 6873
C410064	ELITE MODEL FAST WHITE	Stone models	ISO 6873
C410065	ELITE MODEL FAST SKY BLUE	Stone models	ISO 6873
C410067	ELITE MODEL FAST LIGHT CREAM	Stone models	ISO 6873
C410069	ELITE MODEL FAST LIGHT CREAM	Stone models	ISO 6873
C410070	ELITE MODEL STEEL BLUE	Stone models	ISO 6873
C410071	ELITE MODEL STEEL BLUE	Stone models	ISO 6873
C410080	ELITE MODEL IVORY	Stone models	ISO 6873
C410081	ELITE MODEL IVORY	Stone models	ISO 6873
C410090	ELITE ORTHO WHITE	Stone models	ISO 6873
C410091	ELITE ORTHO WHITE	Stone models	ISO 6873
C410092	ELITE ORTHO WHITE	Stone models	ISO 6873
C410100	ELITE ARTI WHITE	Stone models	ISO 6873
C410105	ELITE ARTI FAST WHITE	Stone models	ISO 6873
C410107	ELITE ARTI FAST WHITE	Stone models	ISO 6873
C410150	ELITE ROCK FAST SANDY BROWN	Stone models	ISO 6873
C410151	ELITE ROCK FAST SANDY BROWN	Stone models	ISO 6873
C410152	ELITE ROCK FAST SANDY BROWN	Stone models	ISO 6873
C410160	ELITE ROCK FAST CREAM	Stone models	ISO 6873
C410200	ELITE ROCK SANDY BROWN	Stone models	ISO 6873
C410201	ELITE ROCK CREAM	Stone models	ISO 6873
C410202	ELITE ROCK SILVER GREY	Stone models	ISO 6873
C410204	ELITE ROCK WHITE	Stone models	ISO 6873
C410205	ELITE ROCK FAST SANDY BROWN	Stone models	ISO 6873
C410207	ELITE ROCK FAST CREAM	Stone models	ISO 6873
C410211	ELITE STONE BROWN	Stone models	ISO 6873
C410214	ELITE STONE PINK	Stone models	ISO 6873

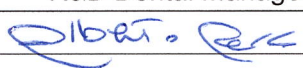
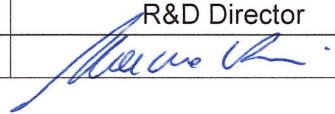
Product code	Product name	Product group	Applied standard(s)
C410220	ELITE MODEL IVORY	Stone models	ISO 6873
C410221	ELITE MODEL STEEL BLUE	Stone models	ISO 6873
C410224	ELITE MODEL FAST SKY BLUE	Stone models	ISO 6873
C410226	ELITE MODEL FAST LIGHT CREAM	Stone models	ISO 6873
C410228	ELITE MODEL FAST WHITE	Stone models	ISO 6873
C410230	ELITE ORTHO WHITE	Stone models	ISO 6873
C410240	ELITE ARTI WHITE	Stone models	ISO 6873
C410241	ELITE ARTI FAST WHITE	Stone models	ISO 6873
C410304	ELITE MODEL IVORY	Stone models	ISO 6873
C410306	ELITE MODEL FAST SKY BLUE	Stone models	ISO 6873
C410308	ELITE MODEL FAST LIGHT CREAM	Stone models	ISO 6873
C410309	ELITE MODEL FAST WHITE	Stone models	ISO 6873
C410310	ELITE STONE NAVY BLUE	Stone models	ISO 6873
C410312	ELITE STONE BROWN	Stone models	ISO 6873
C410313	ELITE STONE AQUA GREEN	Stone models	ISO 6873
C410315	ELITE STONE PINK	Stone models	ISO 6873
C410320	ELITE ORTHO WHITE	Stone models	ISO 6873
C410330	ELITE ROCK SILVER GREY	Stone models	ISO 6873
C410332	ELITE ROCK CREAM	Stone models	ISO 6873
C410334	ELITE ROCK SANDY BROWN	Stone models	ISO 6873
C410336	ELITE ROCK WHITE	Stone models	ISO 6873
C410350	ELITE ARTI WHITE	Stone models	ISO 6873
C410351	ELITE ARTI FAST WHITE	Stone models	ISO 6873
C410400	ELITE MASTER DESERT SAND	Stone models	ISO 6873
C410402	ELITE MASTER DESERT SAND	Stone models	ISO 6873
C410403	ELITE MASTER DESERT SAND	Stone models	ISO 6873
C410404	ELITE MASTER DESERT SAND	Stone models	ISO 6873
C410406	ELITE MASTER SOFT GREY	Stone models	ISO 6873
C410410	ELITE MASTER SANDY BROWN	Stone models	ISO 6873
C410411	ELITE MASTER SANDY BROWN	Stone models	ISO 6873
C410412	ELITE MASTER SANDY BROWN	Stone models	ISO 6873
C410435	ELITE BASE ROYAL BLUE	Stone models	ISO 6873

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C410436	ELITE BASE ROYAL BLUE	Stone models	ISO 6873
C410437	ELITE BASE ROYAL BLUE	Stone models	ISO 6873
C410439	ELITE BASE GREY	Stone models	ISO 6873
C410440	ELITE BASE GREY	Stone models	ISO 6873
C410446	ELITE BASE TERRACOTTA RED	Stone models	ISO 6873
C410447	ELITE BASE TERRACOTTA RED	Stone models	ISO 6873
C410448	ELITE BASE TERRACOTTA RED	Stone models	ISO 6873
C420000	ELITE VEST PLUS	Investments	ISO 15912 for classification
C420002	ELITE VEST CAST	Investments	ISO 15912 for classification
C420010	ELITE VEST LIQUID	Investments	ISO 15912 for classification
C800090	DILUTION BATH WITH CAPACITY UP TO 1 L	Accessories - Hygiene	/
C810037	ZETA 4 WASH	Hygiene	Reg. EU 2004/648
C810042	ZETA 6 HYDRA	Hygiene	Reg. EU 2009/1223 EN 14885
C810043	ZETA 6 HYDRA	Hygiene	Reg. EU 2009/1223 EN 14885
C810044	ZETA 6 HYDRA	Hygiene	Reg. EU 2009/1223 EN 14885
C810046	ZETA 6 DRYGEL	Hygiene	Reg. EU 2009/1223 EN 14885
D510010	PUTTY CUT	Accessories - A-Silicones and C-Silicones	/

Writing	Approval
R&D Dental Manager	R&D Director
	

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