

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
C302025	Hydrogum	1x500g bag	Class I	Rule 5
C302051	Hydrogum	1x18g bag	Class I	Rule 5
C302060	Hydrogum Soft	1x453g bag	Class I	Rule 5
C302044	Hydrogum Soft	1x18g bag	Class I	Rule 5
C302070	Hydrogum 5	1x453g bag	Class I	Rule 5
C302071	Hydrogum 5	2x453g bags in tub	Class I	Rule 5
C302075	Hydrogum 5	1x21g bag	Class I	Rule 5
C302086	Phase Plus	1x453g bag	Class I	Rule 5
C302205	Neocolloid	1x500g bag	Class I	Rule 5
C302230	Neocolloid	1x18g bag	Class I	Rule 5
C302161	Orthoprint	2x500g bags in tub	Class I	Rule 5
C302145	Orthoprint	1x500g bag	Class I	Rule 5
C302171	Orthoprint	1x18g bag	Class I	Rule 5
C302242	Tropicalgin	2x453g bags in tub	Class I	Rule 5
C302240	Tropicalgin	1x453g bag	Class I	Rule 5
C302245	Tropicalgin	1x18g bag	Class I	Rule 5
C302120	Hydrocolor 5	1x453g bag	Class I	Rule 5
C302130	Hydrocolor 5	1x21g bag	Class I	Rule 5
C302140	Pinkalgin 5	1x453g bag	Class I	Rule 5
C302244	Tropicalgin Extra Fast	1x453g bag	Class I	Rule 5
C302241	Tropicalgin Normal	1x453g bag	Class I	Rule 5
C302077	Hydrogum 5	1x453g bag	Class I	Rule 5
C301001	Zetalgin	1x453g bag	Class I	Rule 5
C301004	Zetalgin Chromatic	1x453g bag	Class I	Rule 5
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use:	Alginate for dental impression			
<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 DECLARATION OF CONFORMITY.</p>				
Harmonized Standards applied:	UNI EN ISO 13485 :2012 UNI CEI EN ISO 14971 :2012 UNI EN ISO 10993-1:2010 UNI CEI EN 1041:2013 ISO 15223-1:2016			
Technical standards ref.:	ISO 21563:2013			
EC certificate :	Not applicable			

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Badia Polesine, 15.01.2019