

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			
<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.</p> <p>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, 07.05.2018

Ambrosini Paolo
General Manager