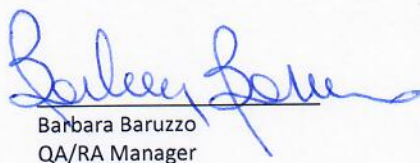


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	NAME	PACKAGING	Classification	Rule
C810000	Zeta 1 Ultra	1 bottle 1000 ml	Class IIb	Rule 15
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use :	Disinfectant and cleaner for Medical Devices			
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, II (excluding 4) and/or V, X, XII ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.				
Harmonized Standards applied:	UNI EN ISO 13485:2016 EN ISO 14971:2012 EN 1041: 2008+A1: 2013 ISO 15223-1:2016 EN 62366:2008			
Technical standards ref.:	Zeta 1 Ultra: DIN EN 13727:2015, DIN EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), DIN EN 13624:2013, DIN EN 14562:2006 (C. albicans, A.niger), DIN EN 14348:2005, DIN EN 14563:2009 (M. terrae, M. avium), UNI EN 14476+A1:2015 (Poliovirus, Adenovirus, H1N1), prEN 16777:2016, DVV/RKI 01.12.2014.			
EC certificate:	According to annex II excluding (4) of the Directive 93/42/EEC N° G1 053618 0027 Rev. 01 valid until 2024/03/19 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany			

Zhermack S.p.A.
Via Bovazecchino, 100
45021 – Badia Polesine (Ro)

Badia Polesine, 23.04.2021


Barbara Baruzzo
QA/RA Manager

Zhermack S.p.A.