Zhermack

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**
C810025	Zeta 3 Foam	1 bottle 750 ml	Class IIb	Rule 15
C810026	Zeta 3 Foam	1 bottle 3000 ml	Class IIb	Rule 15
Classification Rules acc.:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use:	Disinfectants for Medical Devices			

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIREECTIVE 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.

Standards applied:	EN ISO 13485: 2016 +A11:2021 ISO 14971: 2019 EN 1041: 2008+A1: 2013 ISO 15223-1: 2016
Technical standards ref.:	EN 13727:2012+A2:2015, EN 14561 :2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2021, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus), EN 16615: 2015, EN 13697 2015+A1:2019, EN 14885: 2018
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

Badia Polesine, 19.12.2022

Barbara Baruzzo
QA/RA Manager

Zhermack S.p.A.

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