

REVISION HISTORY

Rev #	Date	Revision Originator	Description
7	01.04.2022	Francesca Bottaro	Inclusion of the following changes: -removal of dismissed products, - update of technical standards applied, -removal of Zeta 3 Foam which has a dedicated Declaration of Conformity.
6	23.04.2021	Francesca Bottaro	Inclusion of the following changes: -Update of EC certificate G1 053618 0027 with Rev. 01, -removal of ISO 10993.
5	03.03.2021	Paola Conti	Inclusion of the following changes: -removal of dismissed products, -updating of Harmonized Standards applied. -removal of the Zeta 2 Sporex and Zeta 2 Enzyme products which have a dedicated Declaration of Conformity.
4	02.11.2020	Francesca Bottaro	Update to EN 14476:2013+A2:2019
3	03.04.2020	Francesca Bottaro	Removal of Zeta 7 Solution 1 bottle 125 ml
2	03.06.2019	Francesca Bottaro	The following changes have been included in this version: -Update of EC certificate data -Insertion of the "intended use" -Removal of the Zeta 1 Ultra product which has a dedicated Declaration of Conformity.
1	19.10.2018	Federica Ghirelli	Change of responsible of signature (new qualified regulatory person according to MDR 745/2017)
0	04.09.2018	Federica Ghirelli	This version replaces the former declarations of conformity for Disinfectants rev. [26] dated 30.03.2018.

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
C810023	Zeta 3 Soft	1 bottle 750 ml	Class IIb	Rule 15
C810024	Zeta 3 Soft	2 bottles 2500 ml	Class IIb	Rule 15
C810029	Zeta 3 Soft	1 bottle 125 ml	Class IIb	Rule 15
C810027	Zeta 3 Soft	1 bottle 750 ml	Class IIb	Rule 15
C810028	Zeta 3 Soft	2 bottles 2500 ml	Class IIb	Rule 15
C810032	Zeta 3 Soft	1 bottle 125 ml	Class IIb	Rule 15
C810062	Zeta 3 Wipes Total	1 bag 120 wipes	Class IIb	Rule 15
C810063	Zeta 3 Wipes Total	1 tub 120 wipes	Class IIb	Rule 15
C810064	Zeta 3 Wipes Pop-up	1 bag 100 wipes	Class IIa	Rule 15
C810048	Zeta 7 Solution	1 bottle 1000 ml	Class IIa	Rule 15
C810050	Zeta 7 Spray	1 bottle 750 ml	Class IIa	Rule 15
C810040	Zeta 5 Power Act	1 bottle 1000 ml	Class IIa	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 EN ISO 14971: 2012 EN 1041: 2008+A1: 2013 ISO 15223-1: 2016			
Technical standards ref.:	Zeta 3 Soft: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus,). Zeta 3 Wipes Total: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus). Reduction Factor efficacy of wipes (prEN 16615:2013, 10 min contact time): R>4Log vs. S. aureus, E. hirae, R>3Log vs. C. albicans, P. aeruginosa. Zeta 3 Wipes Pop-up: EN 14476:2013+A2:2019 (HBV, HCV, Adenovirus, Coronavirus, Norovirus, VRS, Polyomavirus, H1N1, HSV, Rotavirus), NF EN 13697+A1:2019, NF EN 1276: 2010, NF EN 14561: 2007; NF EN 1650+A1: 2013, EN 13624: 2004, NF EN 14562:2006 (C. albicans, A. fumigatus); EN 14348: 2005, EN 14563: 2008 (M. terrae), EN 13727:2012+A2:2015. Zeta 7 Solution: EN 13727:2012 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013+A2:2019 (Vaccinia virus). Zeta 7 Spray: EN 13727:2012 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus). Zeta 5 Power act (bottle/unit dose): EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005 (M. terrae), DVV/RKI:2014, DVV:2012, prEN 16777:2014 (all enveloped viruses, including the blood-borne viruses such as HIV, HBV and HCV, other enveloped viruses such as Herpex simplex virus and virus families such as orthomyxoviridae (including all human and animal			

	influenza viruses like H5N1 and H1N1), filoviridae (ebola virus) and paramyxoviridae (measles virus).
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 Only for Zeta 3 Wipes Pop-up: According to annex V of the Directive 93/42/EEC N°G2 17 07 53618 024 valid until 2022/10/17 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany

Badia Polesine, 01.04.2022



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