

DECLARATION OF CONFORMITY

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Product:	CODE	NAME	INTENDED USE	DESCRIPTION
	C810001	Zeta 1 Ultra	Disinfectant and detergent for surgical and rotating instruments	1 flacone/bottle 5000 ml
	C810000	Zeta 1 Ultra	Disinfectant and detergent for surgical and rotating instruments	1 flacone/bottle 1000 ml
	C810002	Zeta 1 Ultra	Disinfectant and detergent for surgical and rotating instruments	1 x 125ml flacone/bottle
	C810011	Zeta 2 Sporex	Disinfectant and cold sterilizer powder for surgical instruments and endoscopes	1 barattolo/jar 900g
	C 810012	Zeta 2 Enzyme	Disinfectant and detergent powder for surgical and rotating instruments	1 barattolo/jar 1200g
	C810021	Zeta 3 Ultra	Disinfectant for surfaces and equipments	1 flacone/bottle 750 ml
	C810022	Zeta 3 Ultra	Disinfectant for surfaces and equipments	1 flacone/bottle 3000 ml
	C810030	Zeta 3 Ultra	Disinfectant for surfaces and equipments	1 flacone/bottle 125 ml
	C810023	Zeta 3 Soft	Disinfectant for surfaces and equipments	1 flacone/bottle 750 ml
	C810024	Zeta 3 Soft	Disinfectant for surfaces and equipments	2 flaconi da 2.5 l./2 x 2,5 lt bottle
	C810029	Zeta 3 Soft	Disinfectant for surfaces and equipments	1 flacone/bottle 125 ml
	C810027	Zeta 3 Soft	Disinfectant for surfaces and equipments (Classic Fragrance)	1 flacone/bottle 750 ml
	C810028	Zeta 3 Soft	Disinfectant for surfaces and equipments (Classic Fragrance)	2 flaconi da 2.5 l./2 x 2,5 lt bottle
	C810032	Zeta 3 Soft	Disinfectant for surfaces and equipments (Classic Fragrance)	1 flacone/bottle 125 ml
	C810025	Zeta 3 Foam	Foam disinfectant for delicate surfaces and equipments	1 flacone/bottle 750 ml
	C810026	Zeta 3 Foam	Foam disinfectant for delicate surfaces and equipments	1 flacone/bottle 3000 ml
	C810060	Zeta 3 Wipes	Disinfectant wipes for surfaces and equipment	1 barattolo/tub 120 wipes
	C810061	Zeta 3 Wipes	Disinfectant wipes for surfaces and equipment	1 busta/bag 120 wipes
	C810062	<i>Zeta 3 Wipes Total</i>	<i>Disinfection and cleaning of medical devices</i>	<i>1 busta/bag 120 wipes</i>
C810063	<i>Zeta 3 Wipes Total</i>	<i>Disinfection and cleaning of medical devices</i>	<i>1 barattolo/tub 120 wipes</i>	
C810064	<i>Zeta 3 Wipes Pop-up</i>	<i>Disinfection and cleaning of medical devices</i>	<i>1 busta/bag 100 wipes</i>	
C800061	Zeta 5 Unit	Disinfectant, detergent and deodorant for surgical aspirators	1 flacone/bottle 5000 ml	
C810048	Zeta 7 Solution	Liquid disinfectant for impressions	1 flacone/bottle 1000 ml	
C810049	Zeta 7 Solution	Liquid disinfectant for impressions	1 flacone/bottle 5000 ml	
C810052	Zeta 7 Solution	Liquid disinfectant for impressions	1 flacone/bottle 125 ml	
C810050	Zeta 7 Spray	Spray disinfectant for impressions	1 flacone/bottle 750 ml	

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1	08/07/08	Prima emissione
2	05/08/08	Inserimento start CE marking
3	09/09/08	Aggiunto Zeta 3 Wipes
4	18/03/09	Aggiornato secondo la Direttiva 2007/47/CE
5	09/09/09	Modifica ruolo Sig. Busin
6	18/09/09	Inserimento Zeta 3 Soft Classic
7	03/02/2010	Inserimento confezione 125 ml
8	22/03/2010	Aggiornamento norme
9	23/04/10	Inserimento dati ente certificatore RAP 02/10
10	22/06/2011	Sostituzione bidone da 5 lt. di Zeta 3 Soft con 2 flaconi da 2.5 lt.
11	16/12/11	Aggiornamento certificato CE
12	23/04/2012	Aggiornamento firma
13	02/08/13	Inserimento anno nelle norme tecniche
14	27/08/13	Inserimento Zeta 3 Wipes Total e Zeta 3 Wipes Pop up

	C810051	Zeta 7 Spray	Spray disinfectant for impressions	1 flacone/bottle 3000 ml
	C810053	Zeta 7 Spray	Spray disinfectant for impressions	1 flacone/bottle 125 ml
Classification:	CLASS IIa: Zeta 3 Ultra, Zeta 3 Soft, Zeta 3 Soft Classic, Zeta 3 Foam, Zeta 3 Wipes, <i>Zeta 3 Wipes Total</i> , <i>Zeta 3 Wipes Pop-up</i> , Zeta 7 Solution, Zeta 7 Spray. CLASS IIb: Zeta 1 Ultra, Zeta 2 Sporex, Zeta 2 Enzyme, Zeta 5 Unit. RULE 15 ANNEX IX OF THE MDD 93/42/CEE amended by 2007/47/CE			
WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/CEE AMENDED BY 2007/47/CE FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.				
Standards applied:	UNI EN ISO 9001:2008			
Harmonised Standards applied :	UNI EN ISO 13485 :2012 UNI CEI EN ISO 14971 :2009 UNI EN 1641:2010 UNI EN 1041:2009 UNI EN 980:2009 UNI EN ISO 14155:2011 UNI CEI EN ISO/IEC 17050-1 :2010 UNI CEI EN ISO/IEC 17050-2 :2005 UNI CEI 70016 :2008			
Applied technical specifications :	<p>Zeta 1 Ultra: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2003, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2007 (Poliovirus, Adenovirus)</p> <p>Zeta 3 Ultra: EN 13727:2012, EN 14561:2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2003, EN 14562:2006 (C.Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2007 (Poliovirus, Adenovirus)</p> <p>Zeta 3 Soft: EN 13727:2012, EN 14561:2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2003, EN 14562:2006 (C.Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus)</p> <p>Zeta 3 Soft Classic: EN 13727:2012, EN 14561:2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2003, EN 14562:2006 (C.Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus)</p> <p>Zeta 3 Foam: EN 13727:2012, EN 14561 :2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2003, EN 14562:2006 (C.Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus)</p> <p>Zeta 3 Wipes: DGHM/VAH guidelines 09/2001, EN 13697 :2001</p> <p>Zeta 3 Wipes Total : EN 13727:2012, EN 14561:2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2003, EN 14562:2006 (C.Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus) <i>Norme riferite alla soluzione. Efficacia di abbattimento delle salviette (Metodo prEN 16615 :2013, 10' contatto): R>4Log vs. S.aureus, E.hirae, R>3Log vs. C.albicans, P.aeruginosa</i></p> <p>Zeta 3 Wipes Pop-up : Battericida EN 1040 :2005, EN 1276 :2009, EN14561 :2006, EN 13697 :2001, Fungicida (A.Niger) EN 1275 :2006, EN 13697 :2001, Lieviticida (c. albicans) EN 1275 :2006, EN 1650 :2008, EN 13624 :2003, EN 1369 :20017, Virucida EN 14476 :2007 H. Simplex virus (HSV) e H1N1.</p> <p>Zeta 2 Sporex: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2003, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus), EN 13704 :2002 (B.Cereus)</p> <p>Zeta 2 Enzyme: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2003, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus)</p> <p>Zeta 7 Solution: EN 13727:2012 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2003 (C.</p>			

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	Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus) Zeta 7 Spray: EN 13727:2012 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2003 (C. Albicans), EN 14348:2005, EN 14563:2008 (M. Terrae), EN 14476:2007 (Poliovirus, Adenovirus, Parvovirus) UNI EN 1041:2009 UNI EN 1641:2010 UNI EN 980:2009
EC certificate :	In according to annex II section 3 of the Directive 93/42/EEC N° G1 11 10 53618 013 valid until 2015/05/05 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany Only for Zeta 3 Wipes Pop-up According to annex V section 3 of the Directive 93/42/EEC N°G2 13 06 53618 017 valid until 2017/10/17 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany
Validity of Declaration of conformity:	Valid until 2015/05/05
Start of CE marking:	Lot number of first CE marking: C810000 Zeta 1 Ultra 1000 ml: 74399 C810001 Zeta 1 Ultra 5000 ml: 74399 C810021 Zeta 3 Ultra 750 ml: 75574 C810022 Zeta 3 Ultra 3000 ml: 75574 C810023 Zeta 3 Soft 750 ml: 74398 C810024 Zeta 3 Soft 5000 ml: 74398 C810027 Zeta 3 Soft Classic 750 ml: 91773 C810028 Zeta 3 Soft Classic 5000 ml: 91773 C810025 Zeta 3 Foam 750 ml: 74768 C810026 Zeta 3 Foam 3000 ml: 74768 C810060 Zeta 3 Wipes Tub 120 pcs: 114167 C810061 Zeta 3 Wipes Bag 120 pcs: 114167 C810062 Zeta 3 Wipes Total Bag 120 pcs: 164717 C810063 Zeta 3 Wipes Total Tub 120 pcs: 164717 C810064 Zeta 3 Wipes Pop-up Bag 100 pcs: 3107461 C810011 Zeta 2 Sporex 900 g: 74408 C810012 Zeta 2 Enzyme 1200 g: 75707 C810048 Zeta 7 Solution 1000 ml: 75762 C810049 Zeta 7 Solution 5000 ml: 75762 C810050 Zeta 7 Spray 750 ml: 75438 C810051 Zeta 7 Spray 3000 ml: 75438 C800061 Zeta 5 Unit: 14/06/1998

Badia Polesine, 27/08/13

Paolo Ambrosini



General Manager
Zhermack SpA

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