

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 |
| | C810012 | Zeta 2 Enzyme | Disinfectant and detergent powder for surgical and rotating instruments | <u>1 barattolo/jar 1000g</u> |
| | 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 | Zeta 3 Wipes Total | Disinfection and cleaning of medical devices | 1 busta/bag 120 wipes |
| | C810063 | Zeta 3 Wipes Total | Disinfection and cleaning of medical devices | 1 barattolo/tub 120 wipes |
| | C810064 | Zeta 3 Wipes Pop-up | Disinfection and cleaning of medical devices | 1 busta/bag 100 wipes |
| | 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 |

| REVISIONE | DATA | DESCRIZIONE |
|-----------|------------|--|
| 1 | 06/07/06 | Prima emissione |
| 2 | 06/08/06 | Intervento Unit CE marking |
| 3 | 06/08/06 | Aggiunta Zeta 3 Wipes |
| 4 | 16/03/07 | Aggiornati i certificati CE Dichiarazione 2004/10/CE |
| 5 | 16/03/07 | Intervento su tutte Sp. Bioni |
| 6 | 16/03/07 | Intervento Zeta 3 Soft Classic |
| 7 | 16/03/07 | Intervento con nuove CE marking |
| 8 | 27/03/2010 | Aggiornamenti norme |
| 9 | 27/03/10 | Intervento sui certificati CE marking |
| 10 | 27/03/2011 | Spedizione nuovi CE marking Zeta 3 Soft con Zeta 45/21 L |
| 11 | 16/07/11 | Aggiornamenti CE marking |
| 12 | 23/04/2012 | Aggiornamenti CE marking |
| 13 | 02/02/13 | Intervento per nuove etichette |
| 14 | 27/04/13 | Intervento CE marking Zeta 3 Pop-up |
| 15 | 25/11/13 | Intervento CE marking Zeta 3 Soft |
| 16 | 04/02/2014 | Intervento CE marking Zeta 3 Soft |

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| C810050 | Zeta 7 Spray | Spray disinfectant for impressions | 1 flacone/bottle 750 ml |
| C810053 | Zeta 7 Spray | Spray disinfectant for impressions | 1 flacone/bottle 125 ml |

Classification:
 Wipes Pop-up, 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 13485 :2012
 UNI CEI EN ISO 14971 :2012
 UNI EN 1641:2010
 UNI EN 1041:2013
 UNI EN 980:2009
 UNI EN ISO 14155:2011
 UNI CEI EN ISO/IEC 17050-1 :2010

Technical specifications ref.:

Zeta 1 Ultra: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2013, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2013 (Poliovirus, Adenovirus)
 Zeta 3 Ultra: EN 13727:2012, EN 14561:2006 (S.Aureus, P.Aeruginosa, E.Hirae), EN 13624:2013, EN 14562:2006 (C.Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2013 (Poliovirus, Adenovirus)
 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 (Poliovirus, Adenovirus, Parvovirus)
 Zeta 3 Foam: 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 (Poliovirus, Adenovirus, 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 (Poliovirus, Adenovirus, Parvovirus)
 Zeta 3 Wipes: DGHM/VAH guidelines 09/2001, EN 13697 :2001
 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 (Poliovirus, Adenovirus, Parvovirus) 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
 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 13624:2013, EN 1369 :20017, Virucida EN 14476:2013 H. Simplex virus (HSV) e H1N1.
 Zeta 2 Sporex: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2013, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus), EN 13704 :2002 (B.Cereus)
 Zeta 2 Enzyme: EN 13727:2012, EN 14561:2006 (S. Aureus, P. Aeruginosa, E. Hirae), EN 13624:2013, EN 14562:2006 (C. Albicans, A.Niger), EN 14348:2005, EN 14563:2008 (M. Terrae, M. Avium), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus)
 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 (Poliovirus, Adenovirus, Parvovirus)

| REVIZIONE | DATA | DESCRIZIONE |
|-----------|------------|---|
| 1 | 05/07/08 | Prima approvazione |
| 2 | 06/03/08 | Revisione alla CE marking |
| 3 | 07/09/08 | Aggiunta Zeta 3 Wipes |
| 4 | 15/01/09 | Aggiunta normativa CE della Zeta 7 Solution |
| 5 | 09/04/09 | Mod. Zeta 3 Wipes |
| 6 | 16/09/09 | Intervento Zeta 3 Spray |
| 7 | 10/02/10 | Intervento correttivo Zeta 7 |
| 8 | 25/02/10 | Aggiornamento norme |
| 9 | 23/04/10 | Intervento alla certificazione SMP 10/11 |
| 10 | 27/06/2011 | Spostamento della S.M. di Zeta 3 Spray 1007/2009 da Zeta 1. |
| 11 | 10/07/11 | Aggiornamento certificazione CE |
| 12 | 21/09/12 | Aggiornamento norme |
| 13 | 02/08/13 | Intervento alla CE marking tedesca |
| 14 | 27/08/13 | Intervento alla CE marking Italia, Zeta 3 Wipes, Pop up |
| 15 | 28/11/13 | Intervento alla CE marking Zeta 3 Spray 30ml |
| 16 | 10/01/2014 | Intervento alla CE marking Zeta 7 Spray 125ml |

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| <p>EC certificate :</p> | <p>Zeta 7 Spray: EN 13727:2012 (S. Aureus, P. Aeruginosa, E. Hirae), EN <u>13624:2013</u> (C. Albicans), EN 14348:2005, EN 14563:2008 (M. Terrael), EN <u>14476:2013</u> (Poliovirus, Adenovirus, Parvovirus)</p> <p>In according to annex II section 3 of the Directive 93/42/EEC</p> <p>N° G1 11 10 53618 013 valid until 2015/05/05</p> <p>TUV SUD PS (0123)</p> <p>Ridlerstrasse 65, 80339 Munchen – Germany</p> <p>Only for Zeta 3 Wipes Pop-up</p> <p>According to annex V section 3 of the Directive 93/42/EEC</p> <p>N°G2 13 06 53618 017 valid until 2017/10/17</p> <p>TUV SUD PS (0123)</p> <p>Ridlerstrasse 65, 80339 Munchen – Germany</p> <p>Valid until 2015/05/05</p> |
| <p>Validity of Declaration of conformity:</p> <p>Start of CE marking:</p> | <p>Lot number of first CE marking:</p> <p>C810000 Zeta 1 Ultra 1000 ml: 74399</p> <p>C810001 Zeta 1 Ultra 5000 ml: 74399</p> <p>C810021 Zeta 3 Ultra 750 ml: 75574</p> <p>C810022 Zeta 3 Ultra 3000 ml: 75574</p> <p>C810023 Zeta 3 Soft 750 ml: 74398</p> <p>C810024 Zeta 3 Soft 5000 ml: 74398</p> <p>C810027 Zeta 3 Soft Classic 750 ml: 91773</p> <p>C810028 Zeta 3 Soft Classic 5000 ml: 91773</p> <p>C810025 Zeta 3 Foam 750 ml: 74768</p> <p>C810026 Zeta 3 Foam 3000 ml: 74768</p> <p>C810060 Zeta 3 Wipes Tub 120 pcs: 114167</p> <p>C810061 Zeta 3 Wipes Bag 120 pcs: 114167</p> <p>C810062 Zeta 3 Wipes Total Bag 120 pcs: 164717</p> <p>C810063 Zeta 3 Wipes Total Tub 120 pcs: 164717</p> <p>C810064 Zeta 3 Wipes Pop-up Bag 100 pcs: 3107461</p> <p>C810011 Zeta 2 Sporex 900 g: 74408</p> <p>C810012 Zeta 2 Enzyme 1200 g: 75707</p> <p>C810048 Zeta 7 Solution 1000 ml: 75762</p> <p>C810049 Zeta 7 Solution 5000 ml: 75762</p> <p>C810050 Zeta 7 Spray 750 ml: 75438</p> <p>C800061 Zeta 5 Unit: 14/06/1998</p> |

Badia Polesine, 25/11/13

Paolo Ambrosini



General Manager
Zhermack SpA

| DESCRIZIONE | DATA | DE SCRIZIONE |
|-------------|------------|---|
| 1 | 08/07/08 | Prima versione |
| 2 | 26/08/08 | Invertendo il CE in EUR |
| 3 | 07/09/08 | Aggiunta Zeta 3 Wipes |
| 4 | 18/03/09 | Aggiunta la parola in D- nella 200/4/NCE |
| 5 | 16/04/09 | Modifica della sig. Barac |
| 6 | 18/09/09 | Invertendo Zeta 1 Soft Classic |
| 7 | 03/02/10 | Invertendo Zeta 1 Soft Classic |
| 8 | 23/02/10 | Aggiunta la parola |
| 9 | 23/02/10 | Invertendo il CE in EUR |
| 10 | 27/02/2011 | Invertendo il CE in EUR |
| 11 | 14/11/11 | Aggiunta la parola in CE |
| 12 | 2/04/2012 | Aggiunta la firma |
| 13 | 20/02/13 | Invertendo il CE in EUR |
| 14 | 27/06/13 | Invertendo Zeta 3 Ultra 750ml e Zeta 3 Ultra 3000ml |
| 15 | 25/11/13 | Doppio CE (EN 14563 e EN 14476) |
| 16 | 04/02/2014 | Modifica della sig. Barac |