Zhermack

2100-SOP QARA-015-ALL 2
Rev. 12/10/2018

## REVISION HISTORY

| Rev # | Date | Revision Originator | Description |
|---|---|---|---|
| 8 | 01.04.2022 | Francesca Bottaro | Inclusion of the following changes:<br>-Update list of standards |
| 7 | 23.04.2021 | Francesca Bottaro | Inclusion of the following changes:<br>-update of the EC certificate G1 053618 0027 with Rev. 01. |
| 6 | 23.03.2021 | Francesca Bottaro | Removal of ISO 10993-1: 2009 |
| 5 | 03.03.2021 | Paola Conti | Creation of Zeta 2 Sporex and Zeta 2 Enzyme dedicated Declaration of Conformity due to a Technical file revision. |
| 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:<br>-Update of EC certificate data<br>-Insertion of the "intended use"<br>-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. |

Zhermack

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

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|---|---|---|---|---|
| Manufacturer: | ZHERMACK SPA<br>VIA BOVAZECCHINO, 100<br>45021 BADIA POLESINE (RO) ITALY | | | |
| Authorized EU-representative: | Not applicable | | | |
| **PRODUCT CODE / CATALOGUE NUMBER** | **BRAND NAME** | **PACKAGING** | **Classification** | **Rule** |
| C810011 | Zeta 2 Sporex | 1 jar 900 g | Class IIb | Rule 15 |
| C810012 | Zeta 2 Enzyme | 1 jar 1200 g | Class IIb | Rule 15 |
| Classification Rules acc.: | ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC | | | |
| Intended use : | Zeta 2 Sporex: sterilizer and disinfectant for Medical Devices<br>Zeta 2 Enzyme: disinfectant and cleaner 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.

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| Harmonized Standards applied: | EN ISO 13485: 2016+A11:2021<br>ISO 14971: 2019<br>EN 1041: 2008+A1: 2013<br>ISO 15223-1: 2016 |
| Technical standards ref.: | Zeta 2 Sporex: EN 13727:2012+A2:2015, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C.albicans), EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus), EN 13704:2002 (B.subtilis).<br>Zeta 2 Enzyme: EN 13727:2012+A2:2015, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C.albicans), EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013+A2:2019 (Poliovirus, Adenovirus, Norovirus, Parvovirus). |
| EC certificate: | According to annex II excluding (4) of the Directive 93/42/EEC<br>N° G1 053618 0027 Rev. 01 valid until 2024/03/19<br>TUV SUD PS (0123)<br>Ridlerstrasse 65, 80339 Munchen – Germany |

Badia Polesine, 01.04.2022

Barbara Baruzzo
QA/RA Manager

Zhermack S.p.A.



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