# MANUFACTURER'S DECLARATION OF CONFORMITY

*AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

**FULL QUALITY ASSURANCE PROCEDURES**

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

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| **Manufacturer's name:** | Malmet (Australia) Pty Ltd |
| **Business address:** | 9-11 McKay Avenue<br>Leeton NSW 2705<br>Australia |
| **Medical device(s):** | WDS1S WDS3S<br>WDS1P WDS3P |
| **Classification:** | Class IIb |
| **GMDN code and term:** | 35318 – Washer, decontamination / sanitizing |
| **Scope of application:** | Malmet 'WDS' Series Bedpan / Urinal Bottle and Utensil / Bowl Washer Disinfector |

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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| **Full quality assurance procedures certificate:** | **AU Q00345 Conformity Assessment Certificate**<br>TGA issued conformity assessment certificate – Schedule 3, Part 1 (excluding clause 1.6) of the Therapeutic Goods (Medical Devices) Regulations 2002 - full quality assurance procedures |
| **Design examination certificate (if applicable):** | **N/A** |

**Standards applied:**

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| ISO 9001:2015 | Quality Management System |
| ISO 13485:2016 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| ISO 15883-1:2006 | Washer Disinfectors – Part 1: General requirements, terms and definitions and tests |
| ISO 15883-2:2006 | Washer Disinfectors – Part 2: Requirements & tests for washer disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc |
| ISO 15883-3:2006 | Washer Disinfectors – Part 3: Requirements and tests for washer disinfectors employing thermal disinfection for human waste containers |
| IEC 61010-1:2010+AMD1:2016 | Safety requirements for electrical equipment for measurement, control and laboratory use – part 1: General requirements |
| IEC 61010-2-040:2015 | Safety requirements for electrical equipment for measurement, control and laboratory use – part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials |
| IEC60601-1-2: 4.0 2014 | Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard – Electromagnetic disturbances – requirements and tests |
| AS 5369:2023 | Reprocessing of reusable medical devices and other devices in health and non-health related facilities |
| IEC 62304:2006+AMD1:2015 | Medical device software – Software life cycle processes* partial compliance:<br>Clause 6 Software maintenance process<br>Clause 7 Software Risk Management Process<br>Clause 9 Software problem resolution Process |
| ISO 15223-1:2021 | Symbols for Labelling |
| WMTS 104:2018 | Technical specification for plumbing and drainage products Appliances (miscellaneous) |
| ISO 14971:2019 (E) | Medical devices – application of risk management to medical devices |

**Authorised signatory:**

Signature

(Peter Kirkup, CEO)

26/06/2024

Date