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.

Manufacturer's name:	Malmet (Australia) Pty Ltd
Business address:	9-11 McKay Avenue Leeton NSW 2705 Australia
Medical device(s):	ES915S-D ES915P-D ES935S-D ES935P-D ES915S ES915P
Classification:	Class IIb
GMDN code and term:	35318 – Washer, decontamination / sanitizing
Scope of application:	Malmet 'ES-D' Series Bedpan / Urinal Bottle 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.

Full quality assurance procedures certificate:	**AU Q00345 Conformity Assessment Certificate** 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:

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 15883-3:2006	Washer Disinfectors – Part 3: Requirements and tests for washer disinfectors employing thermal disinfection for human waste containers
ISO 15883-5:2005	Washer-disinfectors Part 5: Test soils and methods for demonstrating cleaning efficacy
IEC 60601-1-2: 2014 +AMD1:2020	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard – Electromagnetic disturbances – Requirements and tests
IEC 61010-1: 2010+AMD1:2016	Safety requirements for electrical equipment for measurement, control and laboratory use – part 1: General requirements
IEC 61010-2-040:2020	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
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: Clause 6 Software maintenance process Clause 7 Software Risk Management Process 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

26/06/2024

Date

(Peter Kirkup, CEO)