

PRODUCT TECHNICAL DATASHEET

Product Profile & Instructions for Use

MM60 Medicine Measure - graduated

Class I Measuring Medical Device
Volume : 60 ml
Material : Natural Polypropylene
Case Size : 1 x 1500



Intended Use

- A device intended to measure a medicinal product for oral administration to a patient.
- Also used for distribution of tablets and capsules.
- Used in treatment or alleviation of disease, or injury.
- Used with assistance from clinical, nursing and healthcare professionals.
- Used once for a single administration and cleaned between uses (reusable).

Intended User

- Product to be used by injured, disabled, or infirm patients, nursing, and healthcare professionals.

Product Specification

- Graduated at 5ml intervals and numbered in 10ml increments from 10ml to 60ml.
- Tolerance +/- 2ml – critical dosages should be measured with a syringe.
- Can be cleaned in automatic washer disinfectors or hand washed.
- Natural Polypropylene to aid visibility of markings.
- Graduations on inside to aid accuracy.
- Markings can be read from inside or outside of medicine measure.
- Product weight 0.0064 Kg

Packaging Information

Catalogue Number	Case Bar Code (GTIN 14)	Primary Packaging	Secondary Packaging	Case Weight
MM60	15060098135208	Polythene sleeve 1 x 50	Cardboard case 30 x 50	10.14 Kg

Product Symbols

Manufacturer	Date of first use	Catalogue number	UK compliance Approved Body No.	Medical device	Consult instructions	Batch code	Caution	Non-sterile	Absence of natural rubber latex

Do not use if package is damaged	Keep dry	Keep away from sunlight	Unique device identifier



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Manufacturer



- **Warwick SASCo Ltd. Warwick House, Heathcote Way, CV34 6TE, United Kingdom.**
- **Telephone: 0044 (0)1926 422427 E-mail: enquiries@sasco.co.uk**
- **Country of Origin United Kingdom.**

Distributor



Standards

- **Product complies with:**
 - BS EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.**
 - BS EN ISO 15223-1:2021 Medical Devices - Symbols to be used with information to be supplied by the manufacturer.**
 - BS EN ISO 17664-1:2021 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.**
 - BS EN ISO 14971:2019 Medical Devices - Application of risk management to medical devices.**
- **Company compliant to:** **BS EN ISO 13485:2016 Medical Devices - Quality management systems - Requirements for regulatory purposes.**
- **Referenced standard:** **BS EN ISO 15883 Washer disinfectant series.**

Instructions for Use

Storage and Handling

- **Products are supplied safe to handle.**
- **Products are supplied unprocessed in polythene sleeves (primary packaging) and carton outer (secondary packaging).**
- **Shelf life 36 months from date of manufacture, provided the following conditions are met:**
- **Product is stored in its original primary packaging.**
- **Product is stored in clean and dry conditions.**
- **Product is stored off the floor on a shelf or pallet.**
- **Product is not handled roughly or dropped.**
- **There are no specific temperature or humidity storage conditions.**

Preparation

- **Product supplied non-sterile.**
- **Inspect products before processing.**
- **Withdraw damaged products or primary packaging and report to manager.**
- **Wash before use.**
- **Maximum processing temperature 90° C.**

Operating Instructions

- **Product used alone.**
- **Product label on each sleeve of medicine measure with user information.**
- **Tolerance +/- 2ml.**
- **Critical dosages should be measured with a syringe.**



- **Not to be sold separately.**

Cleaning and Disinfection

- **Position products individually, avoiding contact with other items.**
- **Position products to allow water penetration and drainage.**
- **Machine clean in washer disinfectors compliant with ISO 15883.**
- **Use approved detergents, enzymatic or biocide cleaners, suitable for cleaning medical devices (refer to detergent manufacturers' instructions for concentration, temperature, and contact time).**
- **Use detergents and disinfectants with a range between 2pH and 13pH.**
- **Manual cleaning is permissible (refer to detergent manufacturers' instructions for concentration, temperature, and contact time).**
- **Rinse with clean water.**

Sterilization

- **No requirements.**

Inspection Maintenance and Incident Reporting

- **Visually inspect product to identify damage.**
- **Discard damaged product.**
- **Any serious incident that has occurred during the use of this product should be reported to the manufacturer, and the Competent Authority of the territory in which the user is established.**

Disposal

- **End of life is determined by wear and tear, visual inspection, or damage to product.**
- **If product is contaminated treat as clinical waste and dispose of in accordance with clinical waste procedures.**

Warnings/Precautions/Limitations

- **Critical doses should be measured with a syringe.**
- **Do not use abrasive powders or metal brushes as they may cause surface damage.**
- **Do not exceed 90°C.**

Important Information for Processing

- **The information provided by Warwick SASCo is the company's official instructions for this product.**
- **It is the responsibility of the processor to ensure processing is performed in accordance with this information and that personnel, machines and equipment comply with relevant standards and training for processing, to achieve the desired result, which requires validation and routine monitoring of the process.**
- **Any deviation from this information requires evaluation for the effectiveness and potential adverse consequences.**

Additional Information

- **The medicine measure detailed in this datasheet is considered a medical device and is in conformity with the Essential Requirements and provisions of the UK MDR 2002 regulations**



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according to Annex V with Approved Body involvement limited to aspects of manufacture concerning conformity of devices with metrological requirements.

- **Is subject to Approved Body involvement under the supervision of SGS UK Ltd, Unit 202, Worle Parkway, Weston Super Mare, Somerset, B22 6WA United Kingdom, with Approved Body number 0120.**
- **Additional information available on request please contact: enquiries@sasco.co.uk**
- **For additional copies of this datasheet please visit www.sasco.co.uk**

