**DWK Life Sciences Limited**
Unit S77, St. Modwen Park Stoke South,
Gordon Banks Drive, Stoke-on-Trent, ST4 4TW, UK

Registered in England and Wales No.7723574

Tel: +44 (0)1782 444406

www.dwkltd.com
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# PRODUCT SPECIFICATION/CERTIFICATE OF CONFORMITY

| | |
|---|---|
| Brand | **WHEATON®** |
| Product Description | 100, 150 & 250ML POLYSTYRENE CONTAINER RANGE |

## Product Overview

- Ideal for larger volume patient sample collection, transport and storage
- Manufactured from virgin, medical grade, polystyrene
- Fitted with metal flow seal leakproof cap
- Choice of 100ml, 150ml and 250ml
- Supplied sterile by EtO
- Convenient inner packs within each case
- CE Marked in accordance with European Directive 98/79/EC

## Product Specification

| Item Code | Label | Inner Pack Qty | Cap Material | Description | Sterile | Diameter x height mm | Capacity ml | Pack quantity |
|---|---|---|---|---|---|---|---|---|
| 360199 | Plain | 40 | Metal | Polystyrene Container, Plain Label, Metal Cap, Sterile | ETO | 49.8 x 75.8 | 100 | 200 |
| 360200 | No | 40 | Metal | Polystyrene Container, No Label, Metal Cap, Sterile | ETO | 49.8 x 75.8 | 100 | 200 |
| 360201 | Printed | 40 | Metal | Polystyrene Container, Printed Label, Metal Cap, Sterile | ETO | 49.8 x 75.8 | 100 | 200 |
| 360205 | No | 30 | Metal | Polystyrene Container, No Label, Metal Cap, Sterile | ETO | 54.9 x 109.5 | 150 | 120 |
| 360206 | Printed | 30 | Metal | Polystyrene Container, Printed Label, Metal Cap, Sterile | ETO | 54.9 x 109.5 | 150 | 120 |
| 360207 | Plain | 30 | Metal | Polystyrene Container, Plain Label, Metal Cap, Sterile | ETO | 54.9 x 109.5 | 150 | 120 |
| 360250 | Printed | 25 | Metal | Polystyrene Container, Printed Label, Metal Cap, Sterile | ETO | 63.4 x 121.2 | 250 | 50 |
| 360251 | No | 25 | Metal | Polystyrene Container, No Label, Metal Cap, Sterile | ETO | 63.4 x 121.2 | 250 | 50 |
| 360252 | Plain | 25 | Metal | Polystyrene Container, Plain Label, Metal Cap, Sterile | ETO | 63.4 x 121.2 | 250 | 50 |

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**Certificate of Conformity:**

*In accordance with applicable BS EN ISO9001 and BS EN ISO13485 and Company requirements, DWK Life Sciences Limited hereby certifies with respect to the manufactured item described above (collectively, the "Product") that:*

1. Product has been given appropriate visual, and/or mechanical and/or electronic inspection and the results of these inspections indicate that the product meets all agreed upon contractual specifications at the time of its shipment.

2. **Glass:** We certify that the glass product will meet the following:
a) **TYPE I Borosilicate Glass** - Product meets the requirements for the glass grain test limits for Type I Glass when tested according to the current revisions of the USP <660> Pharmacopeias.
b) **Arsenic Extraction** - Product will meet the requirements as described in the current revisions of USP <660> and EP3.2.1 Pharmacopeias for Arsenic Extraction.
c) **TYPE III Soda Lime Glass** – Product meets the requirements for the glass grain test limits according to the current revisions of the USP <660> Pharmacopeias.
d) **Amber Glass** – Product conforms to the light transmission limits specified in the current version of the USP and EP Pharmacopeias.
e) **Hydrolytic Resistance** when indicated above this product conforms to the current version of USP <660>.
*EP compliant vials will either have “EP” listed in the item # or description or “Type I” in the description.
f) **Heavy Metals** are not intentionally added to the glass compositions. Thus, contents of lead, cadmium, mercury and hexavalent chrome are in compliance with the limit values of 100 parts per million by weight for US (TPCH and CONEG) and EC regulations.
g) **Transmissible and Bovine Spongiform Encephalopathy (TSE/BSE)** We certify that containers made from glass and plastic are free of any nonconforming animal derivatives.

3. **Plastic:** We certify that product made from resin material has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

4. **Rubber:** We certify that product made from rubber has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

5. **Aluminium:** We certify that product made from aluminium has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

6. **Hazardous Materials**: DWK’s Glassware does not fall within the scope of the RoHS directive, as our glassware products fall into the exempt status for Medical Devices. Nonetheless, to the best of our knowledge we convey that our glassware does not contain any of the restricted substances outlined by RoHS / WEEE or equivalent directive (e.g. OEHHA Proposition 65).

7. **REACH:** DWK is a manufacturer and supplier of “articles” to our EU customers; we do not manufacture or supply “substances” or “preparations” and our scientific glassware does not involve the “intentional release of substances”. Accordingly, we foresee no registration or pre-registration requirement for the products we supply.

8. **Conflict Minerals:** To the best of our knowledge we convey that our scientific laboratory glassware does not intentionally contain any of the conflict minerals (tin, tantalum, tungsten, or gold) as outlined in Section 1502 of the Dodd-Frank Wall street Reform and Consumer Protection Act.

* Disclaimer: The information herein provided may be based and/or obtained from raw material supplier certificates or, testing reports or, supplier Material Safety Data Sheets or similar.

**Certificate of Analysis authorized by:** **Date: 25/08/2023**



Kevin Marshall, Quality Manager – DWK Life Sciences Limited.

In the event of questions regarding this certificate, please contact certificates@dwk.com.