


DOCUMENT NUMBER: <b>372069-0001</b>	TITLE: <b>Statement of Conformity, Screw Caps</b>	
REVISION: E ECO# EC137774	DOCUMENT CLASSIFICATION: 04-Form	

## STATEMENT OF CONFORMITY

Description: Screw Caps

Function: Tube Capping

Material: Polypropylene (all external screw caps)  
Thermoplastic Olefinic Elastomer + Polypropylene (internal 96 format screw caps)

Part numbers: 65-7572, 65-7573, 65-7574, 65-7575, 65-7576, 65-76000, 66-63100-Y1, 66-63100-Y10, 66-63100-Y11, 66-63100-Y12, 66-63100-Y13, 66-63100-Y2, 66-63100-Y3, 66-63100-Y4, 66-63100-Y5, 66-63100-Y6, 66-63100-Y8, 66-9401, 66-9402, 67-0202-50, 68-53100-Z10N, 68-53100-Z11N, 68-53100-Z12N, 68-53100-Z13N, 68-53100-Z1N, 68-53100-Z2N, 68-53100-Z3N, 68-53100-Z4N, 68-53100-Z5N, 68-53100-Z6N, 68-53100-Z8N

Business name and full address:

Azenta UK Ltd., Gilchrist Road, Irlam, Manchester M44 5AY United Kingdom

The manufacturer declares:

- **Animal Origin Statement (TSE/BSE)**

That the raw materials derived from animal origin used for the manufacture of this product are produced in compliance with EMEA/410/01 rev.3 "Note for Guidance on minimising the risk of transmitting animal spongiform agents via human and veterinary medicinal products" and therefore do not present a risk of BSE/TSE

- **Heavy Metals**

That this product fulfills all the relevant provisions of:

- Packaging and Packaging Waste Directive 94/62/EC with the focus on the "Heavy metal content"
- EN 602:2004-07 "Aluminum and aluminum alloys - Wrought products - Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuff".

- **Quality Assurance**


That the Azenta Quality Management System is certified according to:

- ISO 9001: 2015 "Quality management systems – Requirements"
- ISO 13485:2016 "Medical devices – Quality management systems – Requirements for regulatory purposes"

- **Manufacturing**

That the product is manufactured in accordance with all Azenta internal specifications and applicable procedures and requirements.

Confidential: The information is confidential and is to be used only in connection with matters authorized by Azenta and no part of it is to be disclosed to others without prior written permission from Azenta.

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- **RoHS**

That this product is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and amendment 2015/863/EU.

- **REACH**

That this product fulfills all the relevant provisions of REACH Regulation EC No 1907/2006 (Registration, Evaluation, Authorization and Restriction of Chemicals).

- The part is compliant to the Annex XVII Restrictions
- The part does not contain any of the Article 59 Candidate list SVHCs above 0.1%wt/article.

- **PFAS**

That this product does NOT contain:

- PFOA (perfluorooctanoic acid, CAS No. 335-67-1),
- PFOS (perfluorooctyl sulphonate, CAS No. 1763-23-1)
- or other per- and poly-fluoroalkyl substances (PFAS).

This information is based on a theoretical evaluation of the recipe and the confirmations from Azenta raw material suppliers. Azenta does not intentionally add these substances during production.

- **USP Class VI**

All resins (included pigmented resins) utilized for the tubes and caps have been tested and conform to USP Class VI and in accordance to clause 4.1 ISO 10993-1.

- **Leachables and Extractables**

Final manufactured products have been tested using GC/MS and have been confirmed to be free from detectable levels of Leachable and Extractable contaminants.

- **Cleanroom**

Azenta Life Sciences, Sample Storage Screw Caps are produced in an ISO Class 6 clean room environment with air quality monitoring in accordance with ISO 14644-1.

- **Additional testing**

For this product Azenta Life Sciences certifies the following:

- DNase: Product(s) are free of DNase contamination (Test limit 0.5 ng/ml)
- RNase: Product(s) are free of RNase contamination (Test limit 20 ng/ml)
- DNA: Product(s) are free from any detectable human genomic DNA
- PCR Inhibitor: Products are PCR-inhibitor free
- Pyrogen/Endotoxin: Product(s) are below the acceptance level < 0.05 EU/ml

Signed for and on behalf of Azenta Life Sciences



Print name: Ziri Lalouani

Position: Director of Engineering, Automated Stores, Cryo and Stores Management

Place: Irlam, Manchester

Date: 05/21/2025

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