STATEMENT OF CONFORMITY

Description: Sample Storage Tubes

Function: Sample Storage

Material: Sample Tube: Polypropylene

Storage Rack: Polypropylene (rack base), Polypropylene or Polycarbonate (rack lid)

Part numbers: 64-7532, 65-7505, 65-7506, 65-7509, 65-7510, 65-7514, 65-7515, 65-7516, 65-7517, 65-7531, 65-7532, 65-7533, 65-7534, 65-7634, 65-7640, 65-7641, 65-7642, 65-7643, 65-7644, 65-7645, 65-7646, 65-7647, 65-7650, 65-7651, 65-7652, 65-7653, 65-7660, 65-7661, 65-7662, 65-7663, 65-7664, 65-7665, 65-7666, 65-7667, 65-9201, 65-9203, 65-9302, 65-9303, 66-0700-00, 66-0700-01, 66-0700-02, 66-0700-10, 66-0700-11, 66-0700-12, 66-1000-00, 66-1000-01, 66-1000-02, 66-1000-10, 66-1000-11, 66-1000-12, 66-32033, 66-32033-Y6, 66-32034, 66-32034-L, 66-32034-Y6, 66-32034-Y6-L, 66-32040, 66-32040-Y6, 66-32041, 66-32041-Y6, 66-32041-Y6-L, 66-32042, 66-32042-L, 66-32043, 66-32043-L, 66-32043-Y6, 66-32043-Y6-L 66-32062, 66-32062-Y6, 66-32141, 66-62317, 66-62317-L, 66-62318, 66-62318-Y6, 66-62319, 66-62319-L, 66-62319-Y6, 66-62319-Y6-L, 66-62321, 66-62321-L, 66-62325, 66-62325-1, 66-62325-L, 66-62325-Y6, 66-62325-Y6-L, 66-62326, 66-62326-Y6, 66-62330, 66-62330-L, 66-62330-Y6, 66-62330-Y6-L, 66-62345, 66-62345-Y6, 66-9201, 66-9302, 67-0202-01, 67-0202-02, 67-0202-10, 67-0202-11, 67-0203-01, 67-0203-02, 67-0203-10, 67-0203-11, 67-0753-00, 67-0753-01, 67-0753-02, 67-0753-10, 67-0753-11, 67-0753-12, 67-0754-00, 67-0754-01, 67-0754-02, 67-0754-10, 67-0754-11, 67-0754-12, 67-0755-00, 67-0755-01, 67-0755-02, 67-0755-10, 67-0755-11, 67-0756-00, 67-0756-01, 67-0756-02, 67-0756-10, 67-0756-11, 67-0757-00, 67-0757-01, 67-0757-02, 67-0757-10, 67-0757-11, 67-0758-00, 67-0758-01, 67-0758-02, 67-0758-10, 67-0758-11, 68-0301-00, 68-0301-01, 68-0301-10, 68-0301-11, 68-0301-14, 68-0303-00, 68-0303-01, 68-0303-10, 68-0303-11, 68-0303-14, 68-0701-00, 68-0701-01, 68-0701-02, 68-0701-10, 68-0701-11, 68-0701-12, 68-0702-00, 68-0702-01, 68-0702-02, 68-0702-10N, 68-0702-11N, 68-0702-12N, 68-0703-00, 68-0703-01, 68-0703-02, 68-0703-10, 68-0703-11, 68-0703-12, 68-0704-00, 68-0704-01, 68-0704-02, 68-0704-10, 68-0704-11, 68-0704-12, 68-0801-00, 68-0801-01, 68-0801-10, 68-0801-11, 68-0802-00, 68-0802-01,

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68-0802-10, 68-0802-11, 68-1001-00, 68-1001-01, 68-1001-02, 68-1001-10, 68-1001-11, 68-1001-12, 68-1002-00, 68-1002-01, 68-1002-10N, 68-1002-11N, 68-1003-00, 68-1003-01, 68-1003-10, 68-1003-11, 68-1004-00, 68-1004-01, 68-1004-10, 68-1004-11, 68-4000-00, 68-4000-01, 68-4000-11, 68-4000-31, 68-4000-33, 69-0200-11.

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.

- **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 (**R**egistration, **E**valuation, **A**uthorization and **R**estriction of **C**hemicals).
  - 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.

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- **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 Tubes 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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