


DOCUMENT NUMBER: 378287-0001	TITLE: Statement of Conformity, Storage Racks	
REVISION: D ECO# EC137774	DOCUMENT CLASSIFICATION: 04-Form	

STATEMENT OF CONFORMITY

Description: Storage Racks

Function: Sample Storage Racks

Material: Rack Base: Polypropylene
Rack Lid: Polypropylene or Polycarbonate

Part numbers: 64-9454, 64-9455, 65-9451, 65-9452, 65-9453, 65-9455, 65-9458, 65-9460, 66-51000, 66-51001, 66-51003, 66-51004, 66-51013, 66-51014, 66-51015, 66-51016, 66-51017, 66-51018, 66-51019, 66-51020, 66-51022, 66-51025, 66-51026, 66-51027, 66-61001, 66-61002, 66-61003, 66-9453, 66-9454, 66-9455, 66-9456, 67-0200-00, 67-0203-00, 68-0300-20, 68-4000-21, 68-4000-22, 68-53111-10N, 68-53111-10X, 68-53111-50N, 68-53111-50X, 69-0200-00

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**

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

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- **RoHS**

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 (including 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 Racks are produced in an ISO Class 7 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)
- 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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