


DOCUMENT NUMBER: <b>372636-0001</b>	TITLE: <b>Statement of Conformity, Microplates</b>	
REVISION: E ECO# EC134425	DOCUMENT CLASSIFICATION: 04-Form, Template or Other	

## STATEMENT OF CONFORMITY

Description: Microplate, PCR Plate

Function: Two component microplate

Material: Polycarbonate, Polypropylene & Masterbatch (color)

Part numbers: 4ti-0381, 4ti-0384, 4ti-0384/B, 4ti-0384/G, 4ti-0384/R, 4ti-0384/X, 4ti-0385, 4ti-0386, 4ti-0387, 4ti-0710, 4ti-0710/B, 4ti-0710/G, 4ti-0710/R, 4ti-0711, 4ti-0720, 4ti-0720/B, 4ti-0721, 4ti-0730, 4ti-0730/B, 4ti-0730/G, 4ti-0730/R, 4ti-0730/X, 4ti-0753/757, 4ti-0753/950W, 4ti-0753/C/757, 4ti-0770, 4ti-0770/B, 4ti-0770/G, 4ti-0770/R, 4ti-0770/X, 4ti-0771, 4ti-0772, 4ti-0772/10P, 4ti-0901, 4ti-0911, 4ti-0912, 4ti-0912/10P, 4ti-0951, 4ti-0954, 4ti-0960, 4ti-0960/B, 4ti-0960/G, 4ti-0960/R, 4ti-0960/RA, 4ti-0960/RIG, 4ti-0960/W, 4ti-0960/X, 4ti-0961, 4ti-0961/C, 4ti-0966, 4ti-0970/RA, 4ti-0975/RA, 4ti-1000/B, 4ti-1000/G, 4ti-1000/P, 4ti-1000/R, 4ti-1000/W, 4ti-1000/W-2D, 4ti-1000/X, 4ti-1000/X-2D, 4ti-1001, 4ti-1200/B, 4ti-1200/G, 4ti-1200/P, 4ti-1200/R, 4ti-1200/W, 4ti-1200/X, 4ti-1201, 4ti-1300/X, 4ti-1400/X & 4ti-LB0960/RIG

Business name and full address:

Azenta Life Sciences, The North Barn, Surrey Hills Business Park, Wotton, Surrey RH5 6QT, 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"

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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- **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.

- **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

- **Material(s)**

100 % Virgin Medical Grade Polypropylene, Biocompatible providing an inert low binding surface

- **Well Integrity Test**

Pass – Tube walls are free from holes.

Test method - electronic

- **DNA Test**

Pass - The above specified product is free from any detectable human genomic DNA.

Test method – quantitative PCR; Test sensitivity 2 copies of target gene

- **PCR Inhibitors**

Pass - The above specified product is free from any detectable PCR inhibitors.

Test method – quantitative PCR; Test sensitivity 2 copies of target gene

- **RNase Test**

Pass - The above specified product is free from any detectable RNase contamination.

Test method –fluorometric detection assay, Test sensitivity 3.5e-7 Units/ul (~0.5pg)

- **DNase Test**

Pass - The above specified product is free from any detectable DNase contamination.

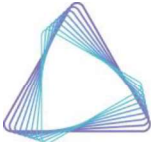
Test method – fluorometric detection assay, Test sensitivity 5.0e-5 Units/ul (~10pg)

- **Pyrogen Test**

Pass - The above specified product is free from any detectable pyrogens.

Test method – LAL, Test sensitivity 0.015EU/ml

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Signed for and on the behalf of Azenta Life Sciences

*Rob Woodward*

Rob Woodward (Nov 2, 2022 15:46 GMT)

Print name: Rob Woodward

Position: Senior Vice President, Global Quality Executive Management

Place: Irlam, Manchester

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