


DOCUMENT NUMBER: 372068-0001	TITLE: Statement of Conformity, Sample Storage Tubes	
REVISION: C EC132107	DOCUMENT CLASSIFICATION: 04-Form	

STATEMENT OF CONFORMITY

Description: Sample Storage Tubes

Function: Sample Storage

Material: Polypropylene

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, 65-7633, 65-7634, 65-7640, 65-7641, 65-7642, 65-7643, 65-7644, 65-7645, 65-7646, 65-7647, 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, 67-0753-03, 67-0753-10, 67-0753-11, 67-0753-12, 67-0754-00, 67-0754-01, 67-0754-02, 67-0754-03, 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, 68-0802-10, 68-0802-11,

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Declaration of Conformity	
Product Name(s)	FreeStyle Blood Glucose Test Strips FreeStyle Lite Blood Glucose Test Strips FreeStyle Papillon Easy Blood Glucose Test Strips FreeStyle Lite Blood Glucose Monitoring System Maintenance Kit
Legal Manufacturer	Abbott Diabetes Care Ltd. Range Road Witney, Oxon, OX29 0YL, UK
Authorised Representative	Abbott B.V. Wegalaan 9, 2132 JD Hoofddorp, The Netherlands
First Date of CE Mark	28 October 2009
GMDN	62537

<u>In Vitro Diagnostic Directive 98/79/EC</u>	
Classification	Annex II, List B
Conformity Route	Annex IV
Notified Body	British Standards Institution (BSI)
Notified Body Identification No.	2797
EC Certificate	CE 603082

Abbott Diabetes Care hereby declare that the above-mentioned products are in conformity with the following legislative acts:

- 98/79/EC *In Vitro* Diagnostics Directive

All supporting documentation is retained under the control of Abbott Diabetes Care Ltd. and made available for review upon request. This declaration is issued under the sole responsibility of, and signed on behalf of the legal manufacturer, Abbott Diabetes Care Ltd.

Signature:	<i>J. Bugler</i>
Name:	Joe Bugler
Position:	Senior Director, ADC Ltd.
Place:	Witney, UK
Date:	<i>20 MAY 2019</i>

— END OF DOCUMENT —



Konformitätserklärung / Declaration of Conformity

Name und Adresse der Firma /
name and address of the company:

MaiMed GmbH
Robert-Koch-Straße 1-7
D-29643 Neuenkirchen
Germany

SRN: DE-MF-000005912

Wir erklären in alleiniger Verantwortung, dass / *We declare under our sole responsibility that...*

das Medizinprodukt /
the medical devise:

MaiMed – stretch
MaiMed – stretch

Verwendungszweck /

Zur sichere Vollflächen-Fixierung von Wundauflagen

Purpose:

To the safe full surface fixation of wound dressings

Basis-UDI-DI /
Basic UDI-DI:

4046153Fixiervlies4V

Risikoklasse gemäß MDR AnhangVIII: /
Risk class acc.MDR Annex VIII:

I

allen Anforderungen der Medizinprodukte-Verordnung (EU) 2017/745 entspricht / *meets all the provisions of the Medical Device Regulation (EU) 2017/745.*

Herstellung und Freigabe der Produkte erfolgen gemäß den in der zugehörigen technischen Dokumentation definierten Spezifikationen, angewandten Normen und normativen Dokumenten. Das Produkt trägt die CE-Konformitätskennzeichnung / *The products are manufactured and released in accordance with the specifications defined in the associated technical documentation, applied standards and normative documents. The product bears the CE conformity marking.*

Diese Konformitätserklärung ist gültig bis zum 23.06.2025 / *This declaration of conformity is valid until 23.06.2025*


Diese Konformitätserklärung wird ausgestellt unter der alleinigen Verantwortung der MaiMed GmbH. / *This declaration of conformity is issued under the sole responsibility of MaiMed GmbH.*

Neuenkirchen, den 23.06.2022

W. Janß / verantwortliche Person MDR-
Artikel15 / responsible person MDR-Article 15:

A handwritten signature in blue ink, appearing to be 'W. Janß', written over a horizontal line.

(Unterschrift / *signature*)

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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 Life Sciences, 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 "Aluminium and aluminium 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"

- **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

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- **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 8 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 the behalf of Azenta Life Sciences

Rob Woodward

Rob Woodward (Oct 13, 2021 12:11 GMT+1)

Print name: Rob Woodward

Position: Senior Vice President, Global Quality Executive Management

Place: Irlam, Manchester

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