# Update on Revision of ISO 4074 Ed 4

Dr William Potter
Stapleford Scientific Services Ltd

# Current Status of Revision

- ISO/DIS 4074 Ed 4 has been approved with comments
  - National Standards Bodies Comments
  - ISO Editor Comments
  - EC HAS Consultants Comments
- Next stage is to resolve the comments
- Timelines
  - Final text to be submitted for FDIS registration by 3rd February 2025
  - FDIS to then be circulated for ballot
  - Target Date for Publication 16th May 2025
  - Limit Date for Project 15th June 2025

# Next Steps

- Meeting with the EC HAS Consultant to review his comments has been completed
- A request to include the ASTM hang and squeeze test for holes will be submitted to the EC
- An editing committee has addressed the ISO Editor's and National Standards Bodies' comments
- A virtual meeting of ISO/TC 157 WG 23 will be convened in early January to agree final edited version
- Final edited text will be registered as an FDIS in January

# Main Changes re ISO 4074:2015

- Many editorial changes have been made to comply with latest ISO Directives
- The electrical test for freedom from holes in Annex M has been amended to improve the probability of finding small holes in the teat (reservoir tip) and closed end of the condom
- A new Annex Q has been added specifying procedures for verifying that the test methods for freedom from holes described in Annex M and ASTM D3492 are meeting specified performance requirements

- Improvements have been made to the inflation test procedure specified in Annex H
- The condom handling procedures described in ISO/TR 19969:2018 have been integrated into Annex H, testing for burst properties, and Annex M, testing for freedom from holes
- The use of technical grade propan-2-ol is permitted for removing lubricant from condoms when determining the lubricant quantity according to Annex C
- Annex G clarifies that a Stomacher® is a specific type of mixer that may be used along with other types of mixers when preparing samples for microbiological testing of condoms. Some amendments to the test procedures have been made based on current best practices

- An alternative dry vacuum method for testing the integrity of individual condom containers has been included in Annex N. This method provides extra security against leakage, for example when condoms are being shipped by air freight or to high altitude countries
- Annex K has been updated to provide clearer and more detailed information about conducting real time stability tests
- Annex L has been updated to include a more rapid accelerated stability test at 70 °C to assess the effect of process and formulation changes on the stability of a product and provide a stress test for condoms that might be stored in high temperature environments

- Annex O has been made normative  and amended to include a new section to verify that technicians can mount the condoms at the correct inflation length on the burst tester
- Annex P has been made normative – significantly extending the range of permitted condom sizes
- A statement has been added to Annex A regarding sample sizes for reduced inspection

# Questions???

- Thank you for your attention