TECHNICAL SPECIFICATION

Automated Infectious Filling Line and Blood Tube Labeller

Filling Machine:

The filling machine needs to:

- Accurately deliver biological solutions into 7ml Blood Tubes meeting specification ISO 6710:2017; Single-use containers for human venous blood specimen collection with a CV of 3%
- Have the ability to 'uncap' the tubes if required
- Handle a range of biological media / fluids including Plasma, Blood, Non-viscous Sodium Chloride (NaCl 0.9 %) with a similar viscosity to these fluids
- Fill volumes between 0.25ml – 5ml and recap with a torque 0.5Nm-1.0Nm
- To accommodate a 15L of bulk solution at room temperature 18-22ºC
- To stir the bulk solution- or accommodate magnetic stirrer
- To fill between 3,000 and 5,000 blood tubes in 6 hours
- Reject any tube that has no cap, a cap screwed on the wrong way, with the wrong torque or if the liquid fill is missing or incorrect
- Give a yield of 98% acceptable vials compared to the total number presented to the machine
- The machine must be validated to ISO 13485
- Have a counter within the logic control to count the number of vials / tubes processed during a batch. At the end of the batch, the counter will be reset for the start of the next batch. A total counter is also to be provided that counts the number processed since commissioning which will not be re-settable.
- A peristaltic pump/ positive displacement syringe dosing system with disposable feed tubes with a short length to the filling point to minimise loss of product. All parts or tubing that have product contact should be able to withstand sterilisation in an autoclave at 121ºC for 20 minutes either for sterilisation before the fill or decontamination after the fill. Disposable systems would be acceptable.
- Dosing Needles, if required, should be removable and able to withstand sterilisation in an autoclave at 121ºC for 20 mins. There are to be 3 sets of needles for each size that covers the filling range, disposable systems would be acceptable.
- Dead volumes to be kept to a minimum to avoid wastage of product at the end of a fill. A max of 50 ml hold-up volume is desirable.
- A printable production report should be produced at the end of each production run detailing the date, batch code (input by operator at beginning of run- up to 20 digits and or numbers with forward slash and – options i.e 20/420-002 or QCRURUBIgMQC1), number of tubes filled, number of rejects, start time and end time.
- Fit within the current Class 1 Microbiological Safety Cabinet (MSC) with dimensions 2190mm long and 810mm high with a width of 700mm narrowing to 480mm at the top of the cabinet. The cabinet is housed within room 3.22 in CBRM which is a CL 3 laboratory. A drawing of the existing MSC is provided in **Appendix B** and a drawing showing its position within room 3.22 is provided in **Appendix C**.
- If a replacement MSC is necessary it should fit in the position shown on the plans so that one window and the camera systems must remain unobscured, details to be checked by the contractor. The position of room 3.22 within CBRM is provided in **Appendix D**.
- The filling line is to fit within the existing room without any modifications. If modifications are required then these will need to be discussed with the client and included in the cost of the works.
- Automated decontamination of filled vials / tubes prior to removal from cabinet
- Be able to be fumigated with formaldehyde at room temperature and relative humidity of 80% and will need to be IP 55 rated as a minimum.
- The base of the machine must be flat easy to clean without any holes or crevasses where the biological solutions can enter. The material must be compatible with aggressive sterilisation disinfectants using the following:
    - Formaldehyde
    - Neat Microsol

- 70% Alcohol
- Hydrogen Peroxide (H_2O_2)

- The system shall be compliant with Windows 10 and future operating system upgrades
- The system shall be fully updatable and allow for security patches / updates and future releases
- The system shall be encrypted to guard against hacking, could be via SSL secure connection
- The system shall be compatible with Multi Functional Devices (as printers), the site currently uses Canon MFD's -
- Please indicate how the database is stored e.g. servers, cloud etc.
- The PLC/PC is to have open code that can be reprogramed or adjusted by any PLC/PC technician, a backup of any PLC/PC or logic programs are to be provided.

Spares & Disposal

- Remove and dispose of the present filling line.
- A set of critical spares are to be provided together with a list of critical/ non-critical spares and suppliers details.

Commissioning

FAT to be undertaken using a non-hazardous trehalose solution with the required production rate, yields and tolerance of 4,000 sarstedt blood tubes on at least 3 runs.
Tubes and caps will be supplied FOC to enable machine commissioning and FAT.

SAT to be undertaken using a non-hazardous trehalose solution with the required production rate, yields and tolerance of:4,000 sarstedt blood tubes on at least 3 runs.
Tubes and caps will be supplied FOC to enable machine commissioning and SAT.

Full training is to be provided to a maximum of 4 operators & 2 maintenance technicians during both FAT & SAT together with a full set of manuals both electronically (Microsoft Word) and in paper form plus parts catalogues.

CE Marking Directive 93/68/EEC

The machine must be fully CE marked to show that it complies with all European and UK regulations including:

- BS7671: Requirements for Electrical Installations, 18th edition by The IET
- Machinery Directive (2006/42/EC)
- Low Voltage Directive (2014/35/EU)
- EMC Directive (2014/30/EU)

Note: the list is not exhaustive and there may be other directives that apply to this project. It is the responsibility of the Manufacturer to identify all regulations and directives that are relevant to this project and ensure full compliance.

In order to show that compliance to all relevant regulations, a Technical File is to be provided with all the appropriate information. If the Vendor resides outside the EEC, they must have an authorised representative within the EEC who acts on behalf of the vendor and may be addressed by authorities and bodies in the Community instead of the Manufacturer with regards to the Directives.

If the Vendor resides within the EEC, then a Technical file must be supplied with machine with the above information that meets UK and EU requirements post Jan 01 2021

Automatic Labelling Machine:

A labelling machine is required to automatically label blood tubes ISO ISO 6710:2017 and will be situated in room 3.27. The labeller needs to be able to accommodate:

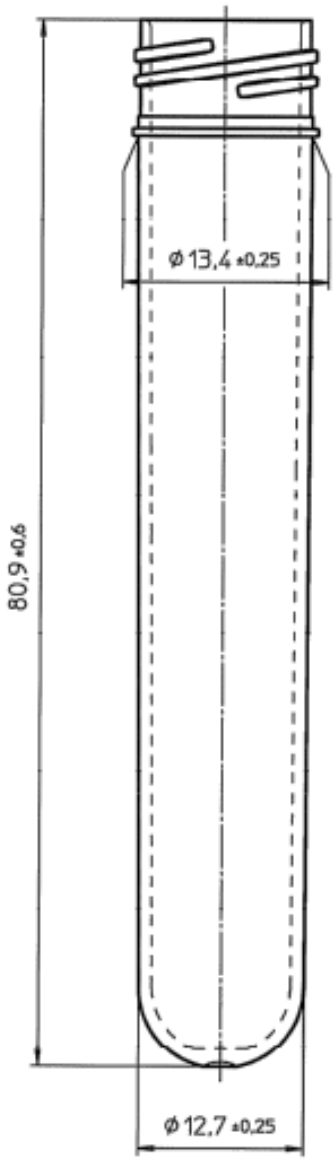
- pre-printed and wound onto a roll with an internal diameter of 45mm.
- Labels 60mm x 40mm wound wide side facing
- A labelling speed of at least 4,000 tubes in 6 hours

APPENDICES

Appendix A – Drawing and Dimensions of Blood tub, capped and un-capped
Appendix B – Drawing of MSC line to fit into
Appendix C – Drawings of room to house filling line and labellers
Appendix D – Floor plan of CBRM

Appendix A – Drawing and Dimensions of Blood tub, capped and un-capped

Medicines & Healthcare products Regulatory Agency



All Dimensions in mm

Screw cap tube, 7 ml, 82x13 mm round base with enclosed cap

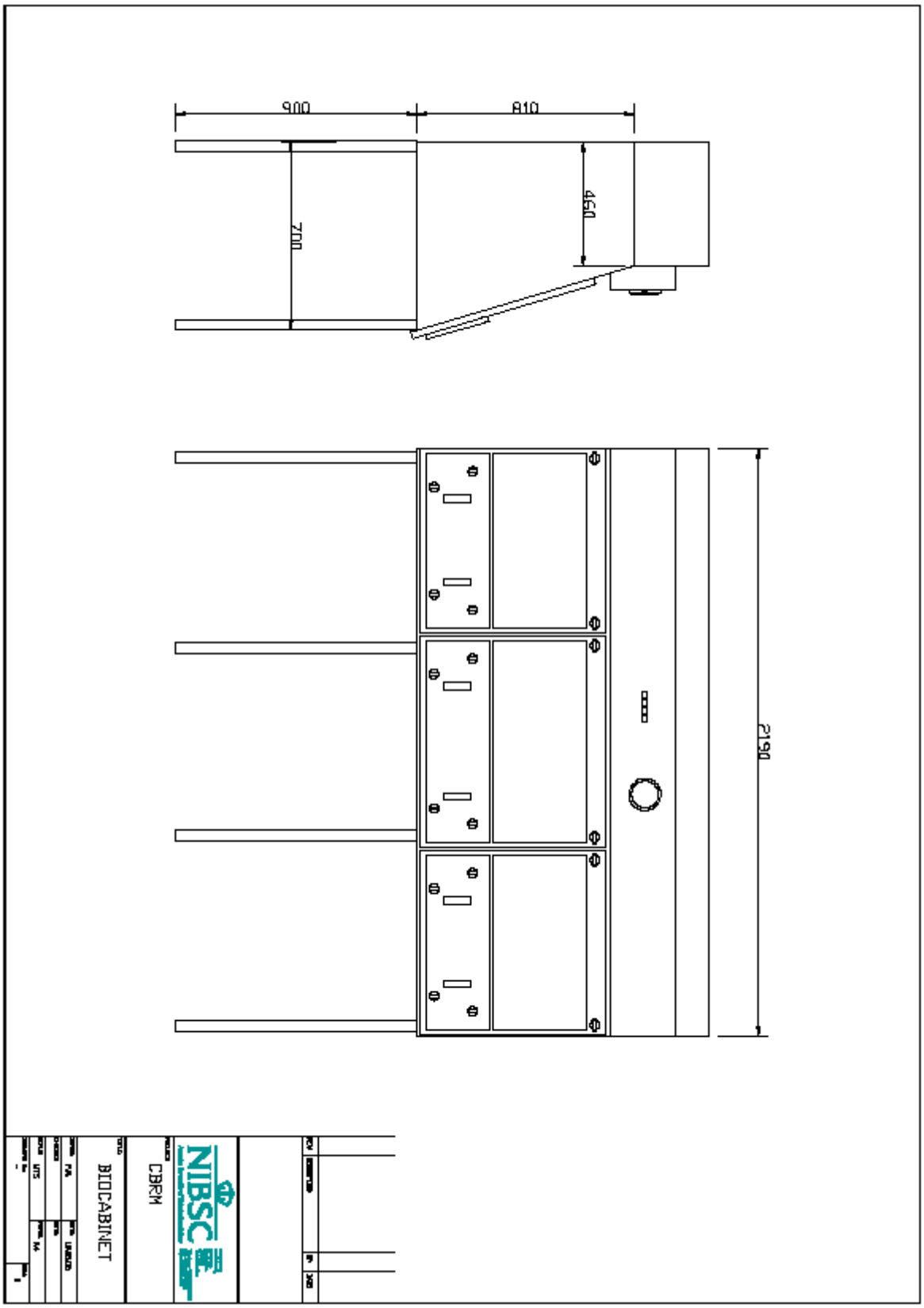
REV:	DESCRIPTION:	BY:	DATE:

STATUS: INFORMATION	DRAWN: AGB	DATE: 03-09-20
	CHECKED:	DATE:
TITLE: 82 x 13mm dia Screw Cap Tube 7 ml Volume	SCALE: 1:1	SHEET: A4
	DRAWING No: 60-550-100	REV: -

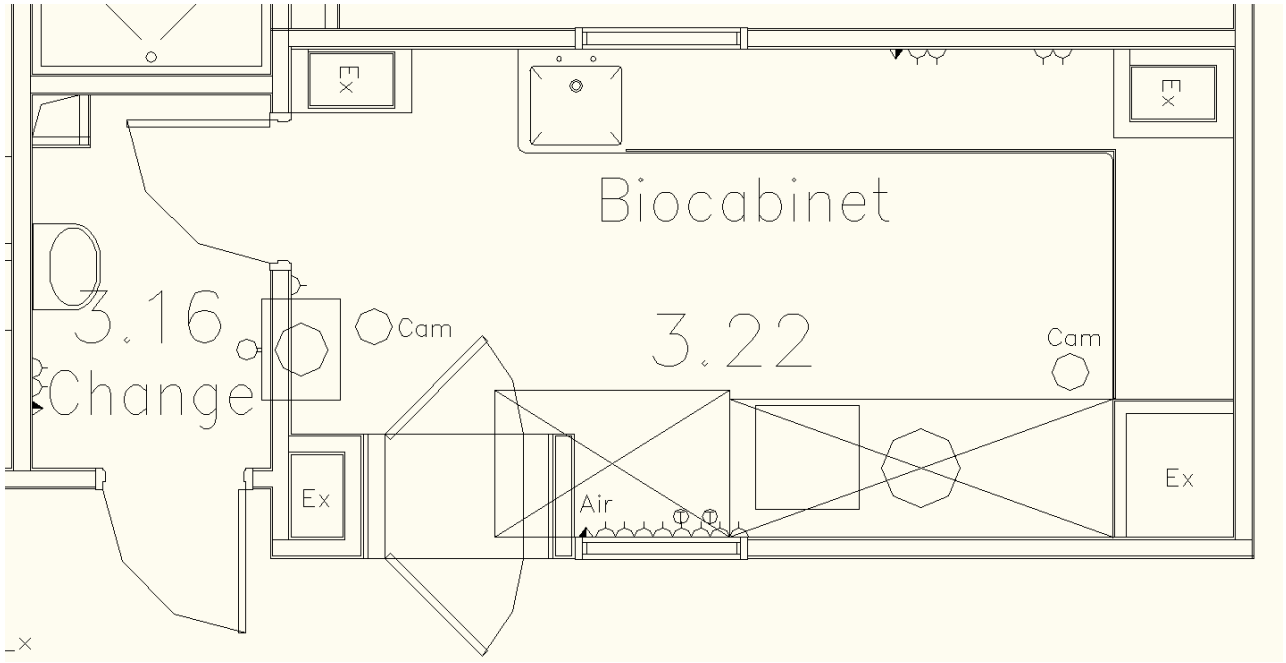
National Institute for Biological Standards and Control — NIBSC — Confidence in Biological Medicines
Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG
Tel: +44 (0)1707 641000 Fax: +44 (0)1707 641050
Website: www.nibsc.org

PROJECT:

Appendx B – Drawing of MSC



Appendix C - CBRM Room 3.22



Appendix D – Floor plan of CBRM