



Separation Scientific SA

Committed to customer service

SABS
ISO 9001

WHO / MPP mRNA Technology
Transfer Program



About Us



- Separation Scientific SA (Pty) Ltd is a local, privately owned company
- Distributes laboratory equipment, consumables and technical services to the Analytical Sciences, Clinical Diagnostics and Life Sciences sector
- The quality management system of Separation Scientific SA (Pty) Ltd meets the requirements of ISO 9001 and SAHPRA.
- Sep Sci is a member and subscribes to the Code of Ethics of the South African Diagnostics Association (SALDA)

SABSS
ISO 9001

We are **“Committed To Customer Service”**



Mission and Vision



To become the preferred distributor in the diagnostics, life sciences and industrial science sector and to provide a total solution to our customers



Sep Sci is a healthcare and industrial science-related group of companies dedicated to supplying high-quality products to its customers. We aim to create a welcoming, fair-minded, and creative work atmosphere, which respects diversity, new concepts and hard work. We are beholden to make a profit to generate a fair return to our shareholders and to finance continued growth in Sub-Equatorial Africa.



To make our mission a reality, those who work within our organization must share the following values and attitudes:

- Personal ethics and commitment in support of this mission in their daily work.
- Commitment to giving service to others, whether internally or externally.
- The desire for personal and professional improvement through continuous training and development of their abilities.
- Generosity towards the group and leadership in order to work as part of a team.
- Commitment to the company's progress and well-being

Benefits of 1 Supplier



Regional offices – local support

1 Customer Support Team

Quality in Supplier-Distributor-Customer relationship

More convenient Forecasting and Budgeting

Central Warehouse and Distribution Channel

Cost Savings





Project Management



Mapping - Understanding the customers needs

Scope | Evaluating requirements and advising on factors to be considered for implementation of project

Managing logistics

Regulatory requirements

Technical Competence

Conduit to bring various service providers together | Preparation and validation of 150 units

Flexibility - Ability to adapt to unforeseen circumstances

Loadshedding | Logistical delay | Site Readiness | Able to work around time constraints

Ensuring Conducive outcomes



Technical Competence

IQOQ Signoff by a certified competent technical engineer

Able to provide a full-service installation, qualification and validation

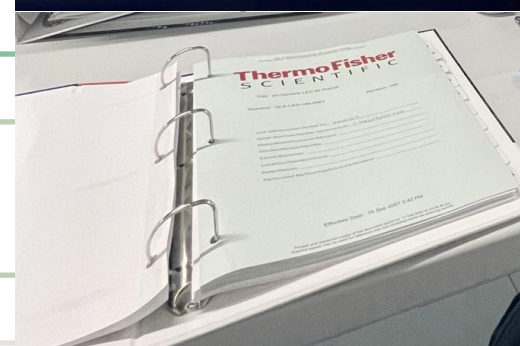
Representative from the customer to review IQOQ and signoff with the certified engineer not always available

Expertise provided to building contractors for technical info regarding:

- Heat extraction
- Fire control and evacuation design

After sales support available to handle repairs and re-validation if necessary

Reputable warranty and support from the supplier





Technical Mapping

- **Scope**

- Mapping Protocol based on Thermo Scientific Protocol of Performance Qualification (PQ)
- Adapted for Full & Empty Mapping with pre-conditioned (Cooled) Gel Packs
- Creation of in-depth document, used to validate the data
- IQ/OQ Certification of ÄKTA Purification system
- IQ/OQ of Knauer LNP systems

- **Identifying and following protocol**

- **Power requirements**

- Backup power
- Staggered turn-on of freezers after power outage to limit load



Mapping in PFF and vigorous testing of the units for temperature recovery as well as alarm operation



DATA interrogation after mapping





Technical Competence

Installation of Temperature loggers



Testing and Validation



Completion of Document packs



Parameter	Original Setting	Changed Setting	Min Value	Max Value	Restored? Yes / No
Control Set Point (-60 °C to -86 °C)	-70 °C	-50 °C	-60 °C	-86 °C	Yes
Cold Alarm (-99 °C to within 5 °C of the temperature set point)	-75 °C	-95 °C	-75 °C	-95 °C	Yes
40.20 Firmware or lower Warm Alarm (-40 °C to within 5 °C of the temperature set point)	NA °C	NA °C	NA °C	NA °C	NA
40.22 Firmware or lower Warm Alarm (0 °C to within 5 °C of the temperature set point)	-65 °C	-40 °C	0 °C	-40 °C	Yes
Primary Offset (-10 °C to +10 °C)	0 °C	0 °C	0 °C	10 °C	Yes
Life Guard (+70 °C to +98 °C)	94 °C	94 °C	70 °C	94 °C	Yes
Extreme Ambient (+32 °C to +40 °C)	37 °C	37 °C	32 °C	40 °C	Yes
Power Recovery Time Delay (0 min to 20 min)	0 min	0 min	0 min	20 min	Yes



Logistics

- ✓ Shipping challenges with delays, trans-shipments and road transport from factory to freight forwarders
- ✓ Arranging of storage facility for the goods prior to delivery
- ✓ Coordination of deliveries - de-crating and unpacking once on site
- ✓ Installation and commissioning of 150 units
 - IQOQ
 - Temperature mapping





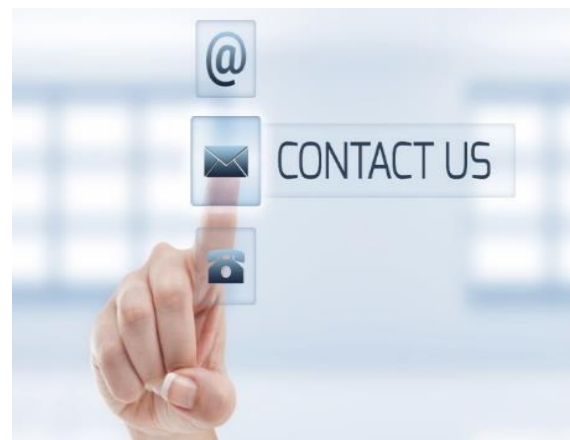
Regulatory Requirements

- Duties payable locally and internationally
- Environmental Gas
- Carbon Footprint
- Local regulations - may vary by country
- Health and safety - flammable gas at the facility





THANK YOU



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