

*Project PlanFor*

*Aleka Holdings Limited [Commercial Registry Number: 137644169]*

Project Title:

**Medical devices (Adhesive Medical Plasters,ZincOxide Plasters, Gauze,  
Bandages..)**

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### List of Abbreviations

Aleka	Aleka Holdings Limited
BRELA	Business Registrations and Licensing Agency
DFID	Department for International Development (UK, currently known as Foreign, Commonwealth and Development Office)
CE	European Health & Safety Product Label
CMPP	COVID-19 related Medical and Pharmaceutical Products
COVID-19	CoronaVirus Disease 2019
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
HDIF	Homeland Development Initiative Foundation
IFRS	International Financial Reporting Standards
Kikela	Kikela Limited
MPP	Medical Plasters for COVID-19 Vaccine Administration Project
NEMC	National Environmental Management Council
OSHA	Occupational Safety and Health Authority
SADC	Southern African Development Community (SADC) countries
SDG	Sustainable Development Goal
TIC	Tanzania Investment Centre
TFRS	Tanzania Financial Reporting Standards
TMDA	Tanzania Medicines and Medical Devices Authority
TZS	Tanzanian Shillings
WHO	World Health Organization

## 1 Executive Summary

Aleka Holdings Limited (Aleka), is a Tanzanian-based company focused on manufacturing high-quality medical supplies, among other business lines, in Dar es Salaam. Since 2020, Aleka Holdings and associated partners have invested over 500,000 USD (over €463,000) to establish a high-quality, commercially viable medical manufacturing facility, to support the COVID-19 response. The facility manufactures locally and internationally certified surgical masks (ISO 13485, 9001, and EN 14683 certified) in an ISO 8 Cleanroom. Aleka wishes to further contribute to supporting the COVID-19 vaccine administration across the SADC region by producing locally and internationally certified medical grade plasters through the Medical Plaster for COVID-19 Vaccine Administration Project (MPP).

The MPP aims to increase access to quality, affordable, and cost-competitive certified medical plasters and enhance regional manufacturing capacities to reduce the reliance on poor quality, uncertified, and expensive medical products. All possible pre-project actions have been completed, allowing for immediate commencement of the project upon securing financing. The project's main activities and milestones are coherent and objectively measurable, starting with the procurement of a plaster-making machine and raw materials, to a fully operational plaster production line, with product sales. Sales projected increase is predicted to be 25%.

Aleka and partners intend to take advantage of being situated within their desired market, in comparison to alternatives, which tend to be imported products. Aleka also aims to support and build the capacities of the local workforce, starting first with Tanzania, and eventually, East Africa, and the rest of the continent. The MPP will also introduce a new technology to Aleka's production range, forming the basis of a new production line. The operationalisation of this technological innovation will build on existing capacities and expertise within the organization. The machines selected are fully automated, producing plasters and packaging them at the same time, and was selected as an overall cost-effective and flexible machine, allowing for a wide variety of plaster shapes and sizes to be produced and packaged pending mold replacement.

Aleka will continue to take extensive COVID-19 precautions in their manufacturing facility to ensure it is fully operational. Employees wear full PPE during production to ensure high-quality medical manufacturing standards are met and to limit the spread of COVID-19. Tanzania has not placed any restrictions on working, manufacturing or otherwise, that would inhibit the operations of the manufacturing line or import of materials. The main project risks are associated with project delays due to either the manufacturing of and/or the shipping and importation of the machine and raw materials. To reduce these risks, Aleka is already in contact with potential suppliers and has identified prices, technical specifications, suitability options, and other criteria that will ensure rapid procurement. Further risks are associated with marketing and sales of the final finished product(s) and establishing a significant market share. Aleka intends to commence marketing and sales, and secure supply contracts, once the project has been initiated as operational.



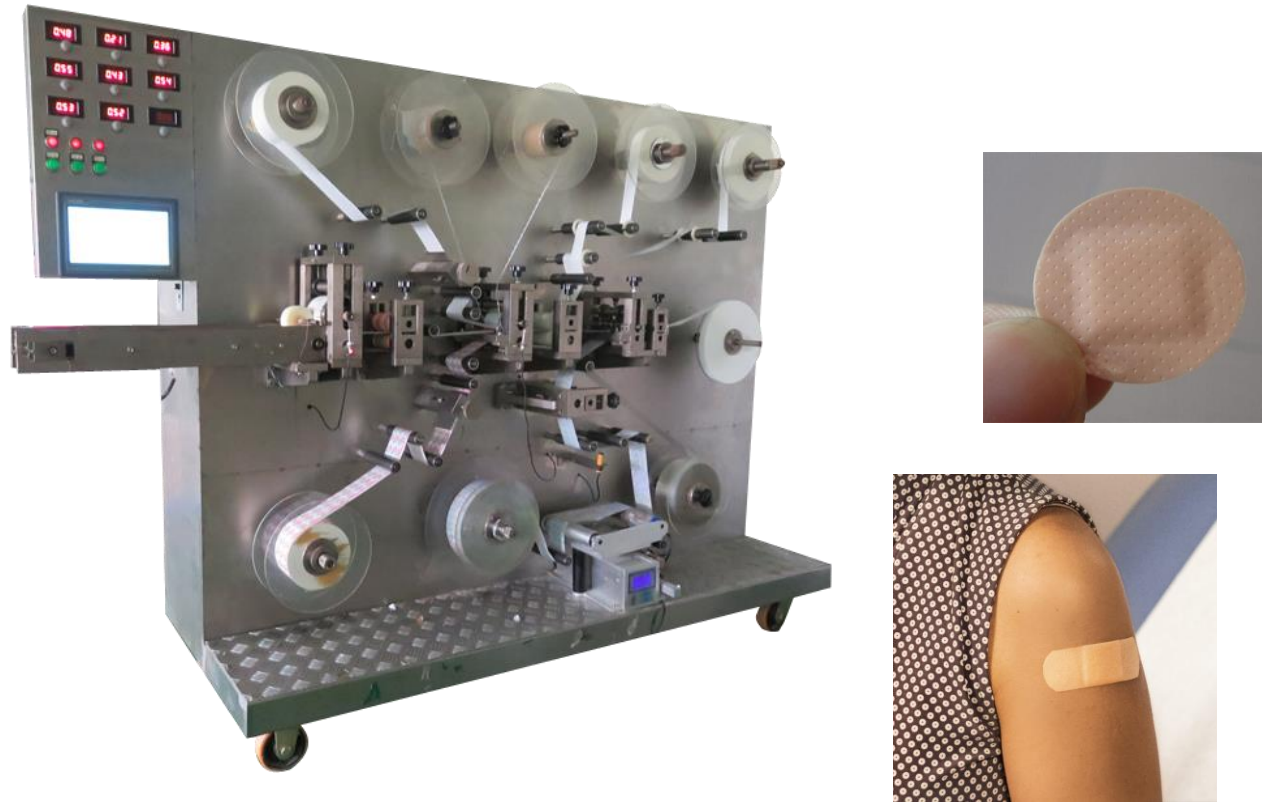


Figure 1: Potential medical plaster making and packaging machine and three variations of potential finalproducts.

## 2 Description of the project:

### 2.1 Description of the product / service provided

The Medical Plaster for COVID-19 Vaccine Administration Project (MPP) intends to support COVID-19 vaccine administration across the SADC region by producing locally and internationally certified medical grade plasters. Aleka Holdings Limited intends to expand its medical manufacturing production to further support regional COVID-19 response by manufacturing certified medical plasters in their ISO 8 Cleanroom and manufacturing facility in Dar es Salaam, Tanzania. Aleka is a Tanzanian-based company currently manufacturing locally and internationally certified surgical masks (ISO 13485, 9001, and EN 14683 certified) in an ISO 8 Cleanroom, in partnership with a small company Kikela Limited, in Dar es Salaam, Tanzania.

The MPP intends to expand Aleka's COVID-19 response support to the wider Southern and Eastern African medical community through increasing access to quality, affordable, and cost-competitive certified medical plasters and enhancing regional manufacturing capacities to reduce the reliance on poor quality, uncertified, and expensive medical products. Medical plasters, like most other imported medical supplies, come in a variety of quality standards, prices, shapes, sizes, and colours. Unfortunately,

quality control on imported medical products inclusive of plasters can be limited in the region, especially due to client financial constraints. Therefore, the project aims to reduce some of these constraints to ensure that medical facilities and individuals can access high-quality affordable plasters to ensure safe and clean vaccine delivery and other medical procedures. Among other factors, this will improve public health by reducing the potential for post-vaccination infections.

The MPP will diversify and increase Aleka's medical manufacturing capacity by adding new production lines, creating a more cost-effective utilisation of the existing manufacturing space, increasing existing manufacturing skills and capacities, overall profits, brand visibility and reputation, and regional customer options for quality medical supplies. The project is anticipated to increase Aleka's capacity utilisation in a sustainable manner, by approximately 20% and sales percentage by approximately 25%, depending on market access during the one year project period.

Since 2020, Aleka Holdings and associated partners have invested over 500,000 USD (over €463,000) to establish a high-quality medical manufacturing facility in Dar es Salaam, Tanzania, to support COVID-19 response commencing with manufacturing certified surgical masks. The overall vision is to manufacture locally and internationally certified medical products that compete on the global scale to ensure improved medical supply access for Southern and Eastern Africa and reduce reliance on poor value-chains, quality, and expensive supplies. As a result of the high investment costs which included the construction, procurement, and upgrading of several fixed factory assets to meet international standards, co-financing is required to ensure the sustainable implementation of the MPP.

Aleka began building their manufacturing facilities in September 2019, by converting existing warehouse space. In April 2020, to support the COVID-19 response, Aleka and partners began investing further capital to upgrade the facility for the production of international quality medical supplies and PPE, commencing with surgical mask production. In preparation for the MPP, cumulative investments valued at over €85,000 in direct costs were used for factory upgrades (not directly associated with the surgical mask production line project), which include the following: i) installing large-scale factory and warehouse partitions and doors; ii) installing three-phase electrical systems to accommodate a variety of machines; iii) installing epoxy floors; iv) construction of changing rooms, gowning rooms, and flow through walking process partitions for medical supply manufacturing; v) ISO 8 cleanroom (with ACs) procurement and installation; vi) low-scale facility upgrades such as improved handwashing and toilet facilities; and vii) other basic factory upgrades. The direct costs (solely used for the procurement and installation of facility upgrades), do not include factory space rental, staff costs, factory registration and compliance costs, legal fees, and any other general startup costs. As such, additional investments of approximately €125,000 have been used for the aforementioned costs. In-kind additional staff (other than COO and factory team members) and investor costs are not included in any of the financial figures stated above. Furthermore, Aleka has utilized previous financing from GIZ, in the form of a develoPPP grant, to support their medical mask production line, thereby demonstrating strong capacities to manage a grant of this nature.

Current Aleka's existing registrations, factory space, and partnerships and regulatory relationships will be directly applicable to and support the MPP. Aleka is registered with the BRELA and the Tanzania Investment Centre (TIC). The manufacturing unit is locally certified by the Tanzania Medicines and Medical Devices Authority (TMDA), Occupational Safety and Health Authority (OSHA), the National Environmental Management Council (NEMC), and has all required fire permits many of which will be directly applicable to the MPP or to rapidly obtaining new MPP specific certifications. Further, Aleka obtained the legally accessible VAT tax exemption for medical manufacturing machines for the import of

the surgical mask manufacturing machine which it will apply for again for the KC-2000-B Plaster Making and Packaging Machine. The MPP will also share the same factory facilities including the ISO 8 Cleanroom used for the existing surgical mask production line, some of the same factory registrations and certifications, and local customers. Further, Aleka has internal quality control mechanisms and standard operating procedures that supersede current local sector standards and requirements which will be transferred to the new production line. Existing relationships with Tanzanian regulatory authorities will support smooth compliance processes for the MPP where new certifications/registrations are required.

Please see below (Figures 2,3,4, 5 and 6) for pictures of Aleka’s current locally and internationally certified surgical mask production line, products and technical production log data sheets, that will be adapted for the MPP.



*Figure 2: Photo of cleanroom air shower entrance*



*Figure 3: Photo of production line in the cleanroom, taken from the door entering the cleanroom*



Figure 4: Photo of women-led production line in full PPE



Figure 5: Photo of Aleka's medical mask, final product

## 2.2 Project Feasibility

Aleka and partners conducted several technical, financial, and optimization-based analyses to understand opportunities for cost-effective manufacturing expansion, as summarized below:

### 1) Feasibility Analysis (General)- Production Opportunities and Overall Expansion Capacity

- *New Production Opportunities-* Aleka undertook an investigation to identify suitable new production line opportunities, which can build on existing skills and capacities, based on ongoing work with non-woven medical manufacturing, thereby ensuring sustainable and reliable diversification. This analysis concluded that the production of medical plasters was a suitable fit.
- *Technical Team Skills & Experience-* An analysis of existing technical skills and experience concluded that the existing team has sufficient experience in operating, troubleshooting, maintaining: i) rotary motor medical manufacturing; ii) plastic packaging machines; iii) working with non-woven fabrics, melt-blown fabrics, and automatic packaging materials; and iv) boxing finished products. The suggested Plaster Making and Packaging Machine (KC-2000-BC) uses similar rotary components, technical dashboards, and manufacturing materials, which we anticipate will allow for easier establishment of a functioning new production line with cross-team support.
- *Production & Storage Space Capacity & Optimal Use-* A comprehensive factory analysis was undertaken to determine the potential to incorporate an additional non-woven manufacturing line, in terms of the spatial dimensions of the existing facility as well as the remaining space within the cleanroom. The conclusion was that the existing ISO 8 Cleanroom has space for an additional manufacturing line and fits the suggested KC-2000-B Plaster Making and Packaging Machine. The factory analysis also found sufficient factory space for raw material and finished product storage for the new production line.
- *Financial Feasibility Analysis-* a general analysis financial analysis was conducted to determine MPP viability, given existing experiences and constraints with and without the grant financing. With grant financing, Aleka and partners can safely invest and, where required, acquire additional financing to immediately implement the MPP. Without grant financing, the potential to diversify and install a new production line is critically reduced, given existing expenses and production dynamics with the surgical mask manufacturing project. The earliest projections for implementing a new production line for plasters is approximately a year from now, thereby hindering Aleka's potential to contribute to affordable and high-quality products to address the COVID-19 pandemic in SADC Member States.

### 2) In-Depth Financial Analysis

- *Cost-Benefit Analysis-* A cost-benefit analysis concluded that an additional production line in the existing factory space (both within the cleanroom and outside) will enhance the overall cost-effectiveness of Aleka's manufacturing. This is principally based on the fact that Aleka's existing operations have high fixed costs, which can be significantly optimized and reduced with an additional production line.
- *Payback Period Analysis-* Basic analysis of the financial models for payback, with and without the grant financing, show that the financial feasibility of the business is highest with grant financing

and the overall payback period is significantly shorter according to current cost estimates. Without grant financing, the addition of a plaster-making production line is not feasible for the proposed timeline of the MPP.

- *Estimated Costs/Pricing:* Aleka has analyzed current costs and trends to estimate the fixed operating expenses of the MPP (please see figure 9 below for details). One quarter of the raw materials will be procured in Tanzania, with the remainder being procured outside. Initial analysis has identified China as the most suitable raw material provider for the plasters. However, pending application acceptance the team will analyze regional procurement opportunities, especially for South Africa where there may be access to some of the materials. Several costs were analyzed, please see examples in Figures 7 and 8 for examples of the most commonly used plaster size (which Aleka intends to produce to support COVID-19 vaccination efforts under MPP).


									
Product size: 19x76mm 2.5Million pcs Qty									
		elastic flat fabric	weight (gsm)	Width mm	length/ roll (meters)	Rolls needed	Need Qty m2	unit price (m2) EXW Factory	Total price (m2) EXW Factory
<b>1</b>	<b>Glued materials (Optional)</b>	absorbent pad	100g fabric+55g glue	78mm	350	136	3903	\$0.972	\$3,793.72
<b>2</b>	<b>Pad</b>	silicon paper	115g	30mm	200	150	900	\$0.700	\$630.00
<b>3</b>	<b>Liner</b>	cold sealing paper	65g	45mm	1000	96	4320	\$0.216	\$933.12
<b>4</b>	<b>Packing</b>	elastic flat fabric	40gsm	95mm	1000	150	14250	\$0.140	\$1,995.00
Total EXW Factory									\$7,351.84
Unit pcs cost (EXW Factory)									\$0.002941

Figure 7: Example 1 of cost analysis for plasters sized 19x76mm

									
Product size: 19x76mm 2.5Million pcs Qty									
		materials name	weight (gsm)	Width mm	length/ roll (meters)	Rolls needed	Need Qty m2	unit price (m2) EXW Factory	Total price (m2) EXW Factory
1	<b>Glued materials (Optional)</b>	adhesive elastic fabric	110g fabric+65g glue	82mm	300	160	3936	\$1.350	\$5,313.60
2	<b>Pad</b>	absorbent pad	115g	30mm	200	150	900	\$0.700	\$630.00
3	<b>Liner</b>	silicon paper	65g	45mm	1000	96	4320	\$0.216	\$933.12
4	<b>Packing</b>	cold sealing paper	40gsm	95mm	1000	150	14250	\$0.140	\$1,995.00
Total EXW Factory									\$8,871.72
Unit pcs cost (EXW Factory)									\$0.003549

Figure 8: Example 1 of cost analysis for plasters sized 19x76mm

More information on reducing risks of imports can be found in the risk section below, however to reduce overall risks bulk material purchasing will take place and will ideally coordinate with surgical mask materials to be consolidated into one shipment. Given the small size of the rolls of raw materials required for this production line, compared to surgical mask production, the team does not anticipate serious procurement issues as a significant amount of materials can fit in any given shipping container.

### 3) Market Analysis

A basic market analysis highlights that Aleka's expected market and customers are domestic and regional: i) national medical supply support facilities (such as MSD in Tanzania), ii) hospitals, iii) health clinics, and iv) pharmacies reached either through existing direct contracts and distributors/wholesalers or new partnerships and contracts. If the contract is awarded, Aleka would immediately commence marketing to seek supply agreements. Anecdotal evidence from discussions with health practitioners within the last month in Dar es Salaam, Tanzania, suggests that there are

further increased supply chain challenges for accessing basic medical supplies, including plasters and bandaging adhesives, due to the joint COVID-19 pandemic issues and the recent oil crisis. Aleka is committed to ensuring the financial stability and success of this project.

Currently, Aleka and partners are unaware of any existing local manufacturing of plasters in Tanzania. All competition for plasters, therefore, comes from importations. Given the existing regulatory framework in Tanzania, in support of industrialization and manufacturing, Aleka hopes to gain a future cost advantage for local production through tax incentives.

Aleka understands that the primary sales and distribution channels for products such as medical plasters are through wholesalers and distributors, importing bulk quantities of plasters and reselling them along existing sales channels. The aim is to utilize these existing sales channels and replace import requirements with high-quality, locally manufactured products. Dar es Salaam is a strategic regional import hub for many of the neighboring land-locked countries that rely on the Dar es Salaam port for all major imports. This creates a competitive advantage for Aleka to sell the plasters in Tanzania and also export to countries that regularly rely on imports through the Dar es Salaam port (e.g. Democratic Republic of Congo, Zambia, and Malawi). Transportation networks and routes are particularly favorable to Zambia and Malawi, providing easier regional market access. Future further and more detailed market analyses will highlight expected domestic and regional sales volumes.

### 2.3 Societal Benefits

The proposed project will contribute to Aleka's ongoing commitment to positive and sustainable social impact. At inception, Aleka's manufacturing focused on reducing plastic pollution in Tanzania through the production of non-woven bags. When the WHO declared a global pandemic, Aleka, with support from GIZ, pivoted production to support COVID-19 prevention and response in Tanzania through manufacturing certified medical masks. Now, Aleka is committed to further contributing to COVID-19 prevention through the production of medical plasters. In the short term, the societal benefits of this project are broad-reaching, from contributing to good health and wellbeing (SDG 3), by ensuring access to essential medical supplies to assist COVID-19 vaccination efforts; to providing decent work for women and youth in manufacturing (SDG 5 and 8). See Section 4.3 for more details). This project will directly contribute to Tanzanians having access to high-quality, affordable plasters, enabling safe and clean vaccine delivery, as well as other medical procedures. Presently, the supply of medical plasters is reliant on expensive imports of unreliable quality, which can result in high levels of (preventable) post-procedure infections. Even when supply is available, it is often too expensive. Though the current focus will be on ensuring sufficient supply of high-quality, certified medical plasters for COVID-19 vaccination measures, in the medium term, Aleka will be ideally positioned to respond to the needs of hospitals and clinics across Tanzania (and the region) in terms of supplying plasters of different shapes and materials, preventing further damage and infection in different types of wounds.

In the long term, Aleka strives to become a leader in locally and internationally certified medical supply manufacturing for Southern and Eastern Africa, aiming to improve the quality and quantity of locally-produced medical supplies. The localization of medical manufacturing value-chains offers immense long-term social benefits. Not only will this improve the quality and quantity of medical

supplies available locally, but it will also provide decent employment, reduce imports and improve regional independence (SDG 3, 8, 10). Aleka aims to act as a buffer between local clinics and global supply-chain issues, price fluctuations, and logistical challenges, thereby ensuring all people, regardless of their economic status, can reliably access high-quality medical supplies.

## 2.4 Environmental Impact

The environmental impact of the MPP will be carefully monitored and will be fully compliant with Tanzanian regulations and environmental requirements. Aleka has already obtained a NEMC certificate (Application Ref: 10597, Registration: EC/EIA/2020/0815), and has existing environmental measures in place that are applicable to the MPP production line. These measures are primarily grounded in the theory that waste reduction is better than waste recycling. As observed in Aleka's surgical mask production line; higher operating standards result in less waste. Aleka, therefore, optimizes machine operations and ensures year-round high standards of machine maintenance, thereby reducing material waste and electricity consumption. Product quality checks are undertaken on a daily basis, and machines are stopped immediately if standards drop, to ensure minimal waste. Currently, any faulty medical masks are recycled and used by Aleka employees, where appropriate. Aleka intends to explore contextually appropriate recycling options for faulty medical plasters, for example, through partnering with facilities that can use them for training purposes.

In the longer term, Aleka's vision to support a localized medical manufacturing value chain will minimize the need for international shipping, significantly reducing the carbon footprint of medical supplies in the SADC region.

## 2.5 Projects' Innovative Features

The MPP will introduce a new technology to Aleka's production range, forming the basis of a new production line. The operationalization of this technological innovation will build on existing capacities and expertise within the organization. €3,500 has been budgeted to support technical assistance for the installation and operations of the plaster-making machine. The machine selected (KC-2000-B) is fully automated, producing plasters and packaging them at the same time.

Furthermore, the KC-2000-B offers increased flexibility in terms of the specific plasters being produced. The immediate focus will be on plasters appropriate for supporting vaccination roll-out (i.e. traditional island plasters, with release papers, measuring 76x19mm). If needed, however, Aleka can change the molds on the KC-2000-BC to produce three different types of plasters, of various sizes and shapes. This would enable Aleka to meet the demands of local and international clinics for larger medical applications, such as full pad plasters for wounds requiring larger absorption.

## 2.6 Technical Assistance

Aleka currently works closely with Tanzania Medicines and Medical Devices Authority (TMDA), Tanzania Investment Center (TIC), National Environmental Management Council (NEMC) Tanzania, and other Tanzanian regulatory authorities to obtain certifications and registrations. For example, we have gained ISO 13485, 9001, and EN 14683 certification for our ongoing production of medical masks. Aleka will

continue to receive technical guidance and support from TMDA, with regard to ensuring medical standards are met during the MPP. Aleka will also seek guidance and technical assistance from the KC-2000-B machine manufacturer for machine installation, operations, and maintenance. Based on previous experience, Aleka will ensure there is stand-by support for ad-hoc operational needs. Furthermore, Aleka will seek trade-related support for regional product sales and distribution.

## 2.7 Product and Services Certification

Aleka has worked, and will continue to work, with a range of bodies including the Tanzania Medicines and Medical Devices Authority (TMDA), Tanzania Investment Center (TIC), National Environmental Management Council (NEMC) Tanzania, other Tanzanian regulatory authorities, and international certifying agents to obtain relevant certifications and registrations.

A summarized outline of relevant certificates and registrations is provided below. As a fully operational company, Aleka has existing relationships with authorities and certifying bodies, and demonstrable experience gaining and complying with relevant certifications and authorizations.

- 1) The Certificate of Incentives from the Tanzania Investment Centre (under authority of Part III, Section 17 (1-8) of Tanzania Investment Act, 1997). Aleka currently holds a Certificate of Incentives (Ref No. 025506).

Aleka also currently holds a Tax Exemption Certificate (Ref: CA/348/650/01) relating to import duties and VAT exemption for raw materials and machines for manufacturing surgical masks, owing to meeting the following requirements:

- A certified copy of the Certificate of company Incorporation
- A copy of the company's Memorandum and Articles of Association.
- A duly filled TIC application forms which are issued by the Centre
- Project business plan
- Evidence of sufficient finance capital available to implement the project
- Evidence of project location
- Company Board Resolution to register the project with TIC.
- An overall covering letter to which all the above are attached.
- Import Duty Exemption For Investors Registered With Tanzania Investment Centre (TIC)

The process and timeline for obtaining this is indicated below:

- Application to be lodged with the Executive Director of TIC.
- Following scrutinization, the approval will be issued within two to three weeks.
- Statutory fee for registration and obtain the certificate of incentive is USD 1100

- 2) Industrial License from Ministry of Industry and Trade, Tanzania

All investment costs that exceed Tsh 100,000,000 are required to be submitted to the Industrial Licensing Board for approval. After the application has been approved, a Temporary Industrial License is issued, lasting three years in order to fulfill the conditions which are written on the license.

All applicants for Industrial License and Certificate of Registration are required to submit the following documents through BRELA:

- Fill Consolidated Form
- Business plan
- Lease agreement /Title Deed

3) Environmental Impact Assessment Certificate, authorized by NEMC (National Environment Management Council)

As stipulated in the 3rd Schedule of the Act and detailed in the 1st Schedule of the EIA and Audit Regulations of 2005, Aleka was required to undertake an Environmental Impact Assessment and currently holds a NEMC certificate (Application Ref: 10597, Registration: EC/EIA/2020/0815).

4) Medical Devices Certificates, authorized by Tanzania Medicines and Medical Devices Authority (TMDA)

a. Premises Registration

In order to import capital goods into the facility, a premises registration is required under Section 18 of the Tanzania Medicines and Medical Devices Act, Cap 219. The requirements include submitting a copy of the Certificate of Registration from Business Registration and Licencing Authority (BRELA), the Tax Identification Number, copies of contracts, sketches of premises layout, etc. The timeline of this requirement commences upon business start-up, and is monitored until all machines are installed and tested. Aleka will continue to comply with this requirement throughout the MPP. Registration Number: TMDA-WEB0120/MDR/0047. Aleka will reapply for this permit for medical plaster production upon securing financing.

b. Business permit for domestic manufacturers;

A permit that is issued concurrently as the premises registration, the business permit for domestic manufacturers is an annual permit. Aleka's current permit is valid until June 30<sup>th</sup>, after which they will apply for renewal through providing a range of existing documents including a copy of the Certificate of Incentives, NEMC Certificate, facility layout, TIN, copies of contracts etc. The fee is based on project capital, within statutory ranges, timeframe is approximately 4 weeks.

c. Marketing Authorization of Medical Devices and In-vitro Diagnostic Devices;

TMDA is mandated to authorize the marketing of medical devices (MD) and in-vitro diagnostic devices (IVDDs) under Section 51 of the Tanzania Medicines and Medical Devices Act on an annual basis. The Authority has established two procedures for marketing authorizations depending on the risk associated with the MD or IVDD. According to The Tanzania Medicines and Medical devices (Control of Medical Devices) Regulations, 2015, all class A, B, C and D devices get market approval through registration while a selected class A devices attain market approval through notification. The timeframe for authorization is up to

4 weeks following submission of samples and conformity tests. The fee is based on project capital, within statutory ranges.

5) ISO & EN ( CE EU, ANSI Z308:1-2015, ISO 13485)

Aleka currently holds nationally and internationally recognized certifications for medical mask production, thereby demonstrating capacities to produce high-quality medical goods.

6) Fire Safety Certificate, authorized by Ministry of Home Affairs, Tanzania

Aleka holds a valid fire safety certificate, as mandated by Tanzanian Law. As per regulations, Aleka's workforce has been trained on fire safety and accident response methods. The facility itself has met all fire safety requirements. Upon installation of the KC-2000-B, a new certificate will be obtained by Akela.

7) Occupational Safety And Health Certificates certified by Occupational Safety And Health Authority, Tanzania (OSHA)

As per the Occupational Health and Safety Act No. 5 of 2003, Aleka ensures that employees work in a safe and healthy environment in accordance with the procedures set out in preventing accidents and occupational diseases. Aleka holds this certificate (Ref No. 203 102 038), allowing for immediate implementation of MPP, if granted. The certification process is twofold:

a. Workplace Registration:

Following online registration, an inspection of the facility, preparation of an the Occupational Health and Safety Policy and Risk Assessment Report, training and follow-ups, which take approximately three weeks and whose cost is depend on the capital investment of the project, workplace registration is authorized.

b. Workplace Compliance:

Following workplace registration, a certificate of compliance is authorized after the preparation of Occupational Safety and Health Policy of the Workplace as per Section 96 of the OHS Act of 2003, a workplace survey and inspection, the development of a Health and Safety Policy. This also takes approximately three weeks and whose cost is depend on the capital investment of the project.

8) National Security Fund (NSS)F & Workers Compensation Fund (WCF) Registration

a. National Social Security Fund

Aleka is registered for the National Social Security Fund was established under the National Social Security Fund Act [Cap. 50 R.E 2018] to provide social security services to members from private and informal sectors. The contribution payable by the employer is twenty per centum (20%) of the employee's monthly wages. Employee's contribute a minimum 10%, employers contribute a minimum of 10%.

b. Workers Compensation Fund (WCF)

As mandated by law, as an employer on Mainland Tanzania, Aleka has registered for the Workers Compensation Fund (WCF), a social security scheme established in accordance with Section 5 of the Workers Compensation Act [Cap.263 Revised Edition of 2015]. All employers in the formal sector from public and private in Mainland Tanzania are required to contribute to the Fund, whereby employers in the private sectors contribute 0.6% while employers in the public sector contribute 0.5% of the employees' earnings. There is no registration fee, timeframe for registration is approximately three weeks after hiring processes are complete

## 2.8 Project Schedule and Milestones

All necessary preparation for the project has already been undertaken by Aleka and partners, through gaining appropriate approvals, certifications, and the investment of approximately 500,000 USD in the factory space and current surgical mask production line needed for medical manufacturing. If approved, the project will commence immediately, upon receiving financing, as per the table below. Activities listed are coherent and realistic and are objectively measurable through the monitoring plan outlined in

Section 4.5.

<b>Main Activities and Milestones</b>	<b>Project Duration 12 Months</b>											
	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>
<i>Main Activity 1:</i> Secure and procure plaster-making and packaging machine, and raw materials (Initial payment to be made within first week of securing financing)	■											
<i>Main Activity 2:</i> Shipping of plaster-making machine and raw materials (minimum 3 months, maximum 4)	■	■	■	■								
<i>Main Activity 3:</i> Commencement marketing and sales, securing supply contracts		■	■	■								
<i>Main Activity 4:</i> Design and order small and large packaging boxes	■	■	■									
<i>Main Activity 5:</i> Establish and prepare distinct storage spaces for raw materials and finished products within existing factory			■	■								
<i>Main Activity 6:</i> Clear machine and raw materials through port and transport to factory (within two weeks from arrival at port)				■	■							
<i>Main Activity 6:</i> Machine installation (one week)				■	■							
<i>Main Activity 7:</i> Operator Training (one week)				■	■							
<i>Main Activity 8:</i> Plaster production line fully operational, with ongoing training and capacity building.				■	■	■	■	■	■	■	■	■
<i>Main Activity 9:</i> Full marketing, sales and distribution				■	■	■	■	■	■	■	■	■
<i>Milestone 1:</i> Initial payment made for plaster-making machine	●											
<i>Milestone 2:</i> Commencement of shipping	●											
<i>Milestone 3:</i> Arrival of shipping in Tanzania				●								
<i>Milestone 4:</i> Plaster-making machine installed, technicians trained					●							
<i>Milestone 5:</i> Plaster production line fully operational					●							
<i>Milestone 6:</i> Completion of GIZ quarterly reporting				●				●				●
<i>Milestone 7:</i> Project completion and audit												●
<i>Legend:</i> ● Milestone; ■ Estimated timeline; ■ Contingency timeline, dependent on external factors beyond direct control of Aleka												

## 2.9 Risk Analysis and Mitigation Measures

SWOT Analysis:

STRENGTH	WEAKNESS
<ul style="list-style-type: none"><li>- Existence of high-quality medical manufacturing facilities</li><li>- Highly qualified and trained staff working in medical supply manufacturing</li></ul>	<ul style="list-style-type: none"><li>- New product line, limited experience manufacturing medical plasters specifically.</li></ul>

<ul style="list-style-type: none"> <li>- Strong track-record in production/supply of medical supplies</li> <li>- Aleka’s strong and positive social impact through job creation for marginalized groups, specifically women and youth.</li> </ul>	
<p><b>OPPORTUNITY</b></p>	<p><b>THREAT</b></p>
<ul style="list-style-type: none"> <li>- No existing certified medical plaster manufacturers in Tanzania offers opportunity to reduce regional dependence on imported supplies.</li> <li>- Regional and national drive for COVID-19 vaccination driving demand for medical plasters.</li> <li>- Existing/pre-COVID-19 market for medical plasters</li> <li>- Opportunity to expand positive social impact through increased job creation for women and youth</li> </ul>	<ul style="list-style-type: none"> <li>- Delays, Stalls and Shortfalls in Supply chain (specifically related to accessibility to machinery and materials)</li> <li>- Spike in shipping costs</li> <li>- Delays to plaster certification</li> <li>- Impact of COVID-19 on staff safety</li> <li>- Uncertain long-term impact of COVID-19 on plaster markets</li> </ul>

Risk Analysis and Mitigation Strategies:

<b><i>RISK DESCRIPTION</i></b>	<b><i>PROBABILITY</i></b>	<b><i>CONSEQUENCE/ IMPACT LEVEL</i></b>	<b><i>MITIGATION STRATEGY + IMPACT TO MANAGE LIKELIHOOD</i></b>	<b><i>ACTIONS IN PLACE + IMPACT TO MANAGE CONSEQUENCE</i></b>
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Delays, Stalls and Shortfalls in Supply chain (specifically related to accessibility to machinery and materials)	Medium	High	<ul style="list-style-type: none"> <li>i) Machine and material sourcing is complete to reduce chance of delays to installation and stalling of production;</li> <li>ii) Procure items immediately when finances are obtained, reducing delays to production;</li> <li>iii) Procure a minimum of 6 months worth of raw materials initially, to ensure sufficient lead time for importing the next batch of materials;</li> <li>iv) Use only individual shipping containers (not consolidated cargo, as these are seeing large delays) to ensure direct transport</li> </ul>	<ul style="list-style-type: none"> <li>i) Positive working relationships with Tanzanian Revenue officials to ensure transparency with regards to shipping delays</li> <li>ii) Shipping insurance</li> </ul>
Increase in shipping costs	Low	Medium	<ul style="list-style-type: none"> <li>i) Secure shipping date and prices upon project being awarded</li> </ul>	N/A (as prices will be fixed upon the signing of contracts. Further, shippers' costs are currently stabilizing despite oil crisis)
Impact of COVID-19 on Staff Safety	Low	Medium	<ul style="list-style-type: none"> <li>i) Maximum 8- 10 workers inside the Cleanroom at one time during a shift to give more space for social distancing. The facility size is small, hence probability is low.</li> </ul>	<ul style="list-style-type: none"> <li>i) All staff will wear full PPE (including masks) while working in alignment with current requirements</li> <li>ii) Existing team of highly trained and qualified individuals able to move from one production line to another, if needed.</li> </ul>
Delays to Plaster Certification Process	Low	High	<ul style="list-style-type: none"> <li>i) Inform Tanzanian Authorities as soon as project is approved (through existing working relationships) to commence approval process</li> </ul>	<ul style="list-style-type: none"> <li>i) Invite Tanzanian Authorities to the facility to finalize certification</li> </ul>
Unpredictable access to domestic and regional plaster sales/markets	Medium	Medium	<ul style="list-style-type: none"> <li>i) Work closely with project provided trade-related support;</li> <li>ii) Work with existing distributors for surgical masks; and</li> <li>iii) Extensive engagement with Tanzania-based and regional medical supply distributors</li> </ul>	

## 2.10 Project advanced actions: Financing, Procurement and Recruitment

Where possible, project advanced actions (e.g. financing, procurement, and recruitment), have already been undertaken. Building on previous support from GIZ, Aleka and partners have made significant investments into their medical manufacturing facility, of approximately 500,000 USD. As such, Aleka has a high-quality ISO 8 Cleanroom, appropriate for the manufacturing of medical plasters. Furthermore, their strong, established and experienced management team will build on their experience in manufacturing medical masks to ensure all new staff has sufficient training and support. In line with GIZ's guidance on procurement, Aleka ensures that three quotations have been requested for the main items, such as the plaster-making and packaging machine and raw materials (for more details, please refer to section 3.1.1.). Upon securing financing, Aleka will be ready to mobilize, aiming to secure and procure the plaster-making and packaging machine, and raw materials, within the first week.

## 3 Description of the Company<sup>1</sup>

### 3.1 Legal Personality and Governance

Aleka Holdings Limited was founded on 18th September 2018. Its Commercial Registry number is 137644169. The company is registered with BRELA & Tanzania Investment Centre (TIC). It is certified by Occupational Safety and Health Authority (OSHA) and the National Environmental Management Council (NEMC).

Aleka Holdings Limited, is a Tanzania-based company focused on manufacturing high-quality consumable and non-consumable household, wholesale, and export products with a factory in Dar es Salaam, Tanzania. At the onset of the COVID-19 pandemic, Aleka began manufacturing and distributing EN 14683 Certified Surgical Masks (ISO 13485, ISO 9001).

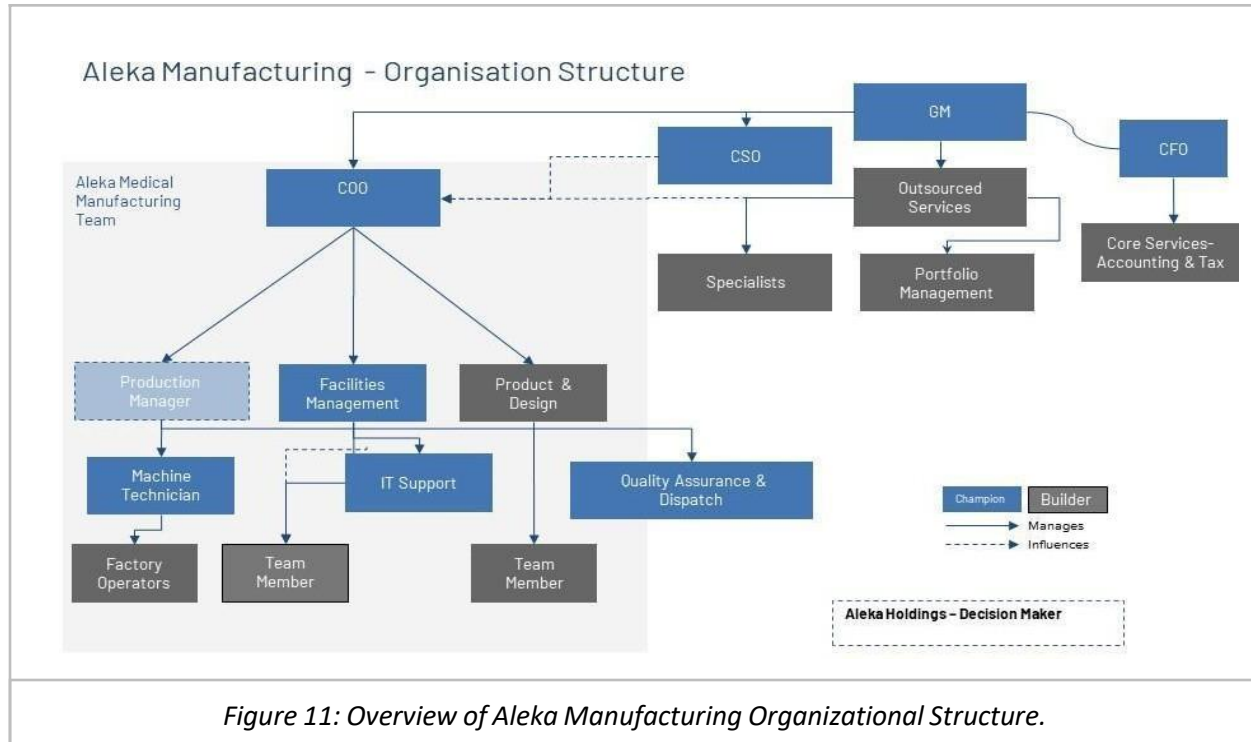
Since 2020, Aleka and partners have made significant strategic investments in fixed assets which enable the introduction of an additional medical manufacturing production line.

Aleka Holdings is a majority Tanzanian-owned and run business with interests in technology advisory, manufacturing, and retail franchising. Its investors are championing the project and injecting initial finances to secure machines and supplies for a baseline production of medical plasters. The company's executive team consists of a CEO, CSO, and COO who manage the investments, financial, technical, and implementation to ensure sustainable results of the MPP.

Please refer to Figure 11 for an overview of Aleka's organizational structure.

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<sup>1</sup> The term "Company" is used to refer to any entity or corporation, including: private, public, for profit, not for profit, academic institution, research centre.



### 3.2 Employment

As a proudly Tanzanian company, Aleka has a strong track record in building local manufacturing skills and aptitude. Aleka currently has 21 full-time equivalent positions and 5 part-time positions, some of which are permanent and others are fixed-term contracts. Aleka is committed to providing an empowering environment for women, with over 90% of our technician and production team being women. We employ both skilled and unskilled workers. We are proud to be capacitating and supporting the next generation of Tanzanian women in technology, hence have a strong focus on building skills for professional development. Aleka maintains high standards of working conditions, ensuring a clean and safe workplace, with regular breaks.

### 3.3 Company's Policies and Procedures

Aleka ensures their company policies and procedures are up to date, and compliant with national and international requirements, through regular reviews. Examples of Aleka's Human Resources, Procurement and Quality Assurance policies are attached to the questionnaire.

#### 3.3.1 Employment and Gender Policies

Aleka's HR manual outlines human capital management guidelines. It outlines the duties and obligations of both employer and employees. It elaborates the measures taken to ensure effective recruitment, which is based on a candidate's ability and acquired competencies to meet the requirements of the vacant position. All job descriptions are reviewed to ensure no direct or indirect discriminatory clauses or language. Open and competitive recruitment processes are undertaken, with vacancies publicly

advertised on multiple platforms. Multiple representatives from Aleka are involved in each stage of the selection and recruitment process and reasons for selection/rejection of applicants are recorded, to ensure no discrimination and equal employment opportunities. Aleka periodically reviews their selection criteria and procedures to maintain a system where individuals are selected, promoted, and treated solely based on their relevant merits and abilities. Aleka actively supports the employment and capacity-development of marginalized groups, hence ensures their factory is an empowering environment for women and young people. Workplace safety and staff wellbeing is supported and maintained through a thorough induction process and regular reviews, in an outlined performance management review system, to discuss employee progress, support and training needs. Appraisal forms are used and provide the basis for identifying training needs and professional development opportunities. Workplace conditions comply with all national regulations. The size of Aleka means that a software-based payroll system is not required for HR management, as current manual systems are sufficient to precisely monitor and calculate payroll and number of person-months employed by the company.

### 3.3.2 Environment Safeguards Policies

Aleka has a strong track record in environmental safeguarding. A full environmental impact assessment for their manufacturing plant was undertaken and approved by Tanzanian authorities, as demonstrated by their NEMC certificate (Application Ref: 10597, Registration: EC/EIA/2020/0815). The impact assessment outlines all necessary steps taken to reduce their environmental impact. This includes optimizing production to ensure minimal waste and pollution, which is monitored on a daily basis. Any waste that is produced is recycled/reused, where possible, and disposed of in a safe manner when recycling is not possible. Commitment to environmental sustainability is driven by management, who take the responsibility to review and improve safeguarding measures on an ongoing basis.

### 3.3.3 Current Corporate Social Responsibility Activities

Aleka is committed to playing a positive role in their community, by considering the environmental and social impact of their business decisions. As such, Aleka has adopted a holistic approach to CSR, ensuring operational initiatives intentionally consider their social impact. As noted above, from an environmental perspective, Aleka undertakes daily reviews to ensure operational efficiency, thereby reducing waste and ensuring minimal environmental impacts. Where appropriate, waste is recycled/reused. For example, faulty medical masks are reused by employees. Furthermore, Aleka ensures a safe and inclusive workspace for all employees and is committed to supporting gender equality and women's empowerment, as demonstrated by their manufacturing team consisting of over 90% women. When Aleka's medical manufacturing sales are established, company management intends to set additional and specific CSR targets, in consultation with employees and local communities.

### 3.3.4 Internal<sup>2</sup> and External<sup>3</sup> Control

Aleka's controls are designed around three key pillars: i) Processes; ii) People; and iii) Technology. People are regarded as the most important pillar with the focus being on ensuring that management and employees act with integrity and respect with both internal and external stakeholders, ensuring processes and policies are adhered to. The company has designed robust and transparent controls to ensure the business continues most effectively. Controls are adapted to ensure that the risk is mitigated

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without negatively impacting business effectiveness, through cross-checking with multiple parties, including directors and Aleka's external auditors, who are recognized by the National Board of Accountants and Auditors. Whenever lapses in controls are noticed, the root cause is established, and actions are undertaken to mitigate the weakness. This is a proactive process that focuses on addressing the lapse. Aleka's model understands the cause as either process, people, or technology. During investigations, confidentiality is maintained and staff is provided only with the information they need to perform their work. Aleka also ensures that key tasks and functions are separated and not performed by one and the same person. For example, the finance team will load a purchasing order, and two directors are required for sign-off.

### 3.3.5 Procurement and Contract Award Procedures

As outlined in Aleka's Procurement and Procedures, to obtain the best value, quantity, and services, it is Aleka's policy to encourage the most competitive and able suppliers to tender for contracts. In doing so, Aleka staff apply procurement procedures with fairness, integrity, and transparency and shall be responsible to prepare standard conditions of the contract.

For low-value quotations (of 10,000,000 TZS or less), staff from the ordering department fill a Purchase Request Form. The procurement and logistics staff then search for quotations from different suppliers who can meet the following requirements, provide proforma Invoices and TRA Receipts, and accept bank transfer or cheque payment. Payment by bank transfer or cheque is encouraged to be used for as many payments as possible, for managing internal control systems.

For goods and services over 10,000,000 TZS, Aleka employs a competitive tendering approach, through an invitation to bid or a request for proposals. At a minimum, three suppliers are considered by the tender committee, which is divided into the technical evaluation committee and the financial evaluation committee as per the agreed evaluation criteria. An evaluation report is prepared and approved by a Managing Director before the contract is awarded.

Aleka staff are not permitted to disclose any privileged information about any project requirements or deprive other vendors of such information that puts another vendor in a more advantageous position over another. This includes revealing the other bids/ quotations prices, terms, and conditions, etc. All information received from vendors is treated confidentially.

To avoid any conflicts of interest, Aleka staff involved in any procurement functions who have a direct or indirect conflict of interest, s/he must declare to the management, and such contracts under exceptional circumstances, with the prior written approval from the management, may be concluded. Failure to make such a declaration is grounds to invoke disciplinary action. Acceptance of offer, payment, solicitation, and/or any form of bribe, commissions, gratuities, or gifts, are unacceptable and subject to disciplinary measures.

The above steps are considered critical to ensuring diversified, fair, and transparent procurement.

### 3.3.6 Quality Assurance Procedure

As outlined in Aleka's Quality Assurance Policies and Procedures (attached to the application form), Aleka upholds a quality-focused culture to ensure the safety of our customers. Aleka hence prioritizes the safety, efficacy, and quality of their products. Their quality assurance policy is based on six fundamental elements outlined below:

1. Customer needs and expectations are the driving force and must be met to succeed.
2. At Aleka Holdings, quality is all encompassing and applies to everything we do.
3. Each person, at Aleka Holdings, is accountable for ensuring product/service quality, performance, and safety.
4. People are the key to the quality of the organization and that is why all Aleka Holdings employees have the appropriate training, education, skills, and experience to carry out their work competently.
5. We are committed to continuously improving the Quality of our products and services. Our continuous improvement journey is part of Aleka Holdings operational excellence program.
6. The attainment of our Quality Objectives is the responsibility of senior management and requires the active participation of each employee of the company, in compliance with the ethical principles and values at Aleka Holdings.

Quality and Site Management is responsible for establishing and maintaining a system for the control of all measuring and test equipment used by each site in all phases of product development, inspection, testing, installation, servicing, and product acceptance. Designated instruments and equipment are calibrated and traceable to recognized standards. The effectiveness of the quality management system and the overall quality performance of manufacturing, distribution, and development operations is monitored and assessed on an ongoing basis to ensure the highest quality outputs.

### 3.4 Project Implementation Monitoring

The MPP will be carefully monitored on an ongoing basis, through key indicators to ensure the project milestones noted above are achieved and results are sustainable. Milestones 1-4 will be monitored and measured according to their completion as per the timeline provided in section 3.1.2. In addition, for Milestone 5, to ensure operational efficiency and compliance, Aleka will undertake thorough reviews, on an ongoing basis, of the medical plaster production line, documenting any deviations. Aleka will continue to use daily digital production records which assess any maintenance needs, as well as the quality and efficiency of the production line. After a stabilization period of approximately three months, daily, weekly, and monthly production targets will be set and monitored (mirroring current processes in place for the production of medical masks). These targets will be realistic and are objectively measurable throughout the duration of the project. Reviews will also include an assessment of technical capacities and gaps, which will also be documented and shared.