

Labour Standards Assurance System (LSAS) Framework

Introduction

Malosa Medical (Malosa) manufactures and supplies a range of single use medical devices around the world.

The company acknowledges its obligations towards customers, employees and communities in which it works and the responsibilities it bears to all parties involved in each of the stages involved in producing our products. To achieve these aims Malosa has developed an Ethical Trading Policy based on the internationally recognised ETI Base Code.

Malosa is committed to achieving high ethical and environmental standards within the business and throughout the supply chain. This policy sets out the requirements and minimum expectations for labour practice. Malosa requires written confirmation from suppliers and contractors that they will comply with the following code of conduct:

Code of Conduct

The following code of practice covers the labour practices we expect from Malosa suppliers, both in the UK and overseas.

Employment is freely chosen

- The company shall not engage in or support the use of forced or compulsory labour, or bonded or involuntary prison labour. Employees are free to leave upon reasonable notice.

Freedom of association & the right to collective bargaining

- Workers, without distinction, have the right to join or form trade unions of their own choosing, and are able to bargain collectively.
- The employer must hold an open attitude towards the activities of trade unions and their organisational activities.
- Worker's representatives are not to be discriminated against and have access to carry out their representative functions in the workplace.
- Where the right to freedom of association and collective bargaining is restricted under law, the employer facilitates, and does not hinder, the development of parallel means for independent and free association and bargaining.

Working conditions are safe and hygienic

- The company will provide a safe and healthy working environment, and will take all reasonable steps to prevent accidents, injury and death in the working environment.
- All workers shall receive regular and recorded health and safety training.
- The company will provide access to clean toilet facilities and to portable water, and if appropriate, sanitary facilities for food storage shall be provided.
- Accommodation where provided, shall be clean, safe and meet the basic needs of the workers.

Child Labour shall not be used

- There shall be no new recruitment of child labour.

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- Companies shall develop or participate in and contribute to policies and programmes that provide for the transition of any child found to be performing child labour to enable them to attend and remain in quality education until no longer a child.
- Children and young persons under 18 shall not be employed at night or in hazardous conditions.
- These policies and procedures shall conform to the provisions of the relevant ILO standards.

Living wages are paid

- Wages and benefits paid for a standard working week meet national legal standards or industry benchmark standards, whichever is higher. In any event, wages should always be enough to meet basic needs, and to provide some discretionary income.
- All workers are to be provided with written and understandable information about their employment conditions in respect to wages before they enter employment.
- Deductions from wages as a disciplinary measure shall not be permitted, nor shall any deductions from wages not provided for by national law be permitted without the expressed permission of the worker concerned.

Working hours are not excessive

- Working hours comply with national laws and benchmark industry standards, whichever affords greater protection.
- Workers shall not on a regular basis be required to work excessive hours, and shall be provided with reasonable and adequate time off.
- Overtime shall be voluntary and shall not be demanded on a regular basis.

No discrimination is practiced

- The company shall not discriminate against any person based on race, caste, national origin, religion, age, gender, disability, marital status, sexual orientation, union membership or political affiliation.

Regular employment is provided

- To every extent possible, work performed must be on the basis of recognised employment relationship established through national law and practice.
- Obligations to employees under labour or social security laws and regulations arising from the regular employment relationship shall not be avoided through the use of labour only contracting, sub-contracting, or home working arrangements, or through apprenticeship schemes where there is no real intent to impart skills or provide regular employment, nor shall any such obligations be avoided through the excessive use of fixed-term contracts of employment.

No harsh or inhumane treatment

- Physical abuse or discipline, the threat of physical abuse, sexual abuse, verbal abuse or other forms of harassment or intimidation shall be prohibited.
- All disciplinary measures should be recorded, be fair, proportionate and fully compliant with local laws.

Protection of the environment

- The company will carry out their activities in accordance with national laws, regulations, administrative practices and policies relating to the preservation of the environment of the countries in which they operate as well as in accordance with relevant international



agreements, principles, objectives, responsibilities and standards with regard to the environment.

To drive compliance, assure effective implementation of this policy and achieve continual improvement, not only within its own business but throughout its supply chain, Malosa commits to:

- Dedicate ownership of the policy to a Management Representative and dedicate operational responsibility to others where necessary.
- Adequately communicate the policy both internally and externally, ensuring that all relevant employees, suppliers and contractors are aware of the policy.
- Recognise our suppliers' ethical and responsible sourcing policies where they are comparable to our own.
- Provide appropriate training, resource and guidance to support the implementation of this policy.
- Require all suppliers to confirm in writing that they have received, understood and are working towards compliance with the policy.
- Regularly review suppliers' commitment to supporting the policy through periodic communication and assessment.
- Maintain an internal system to record and monitor the level of compliance to this policy.
- Cease trading in a responsible way with suppliers demonstrating persistent disregard for the policy, considering the impact this may have on the workers and communities in which the supplier operates.

Malosa requires its suppliers and contractors to:

- Comply with this policy and all applicable laws in the countries in which they operate.
- Communicate the policy to all employees, suppliers, subcontractors, home workers and temporary and contract workers engaged in their supply chain. (Malosa will recognise a Suppliers own policy and standards where comparable to our own).
- Communicate openly and honestly with Malosa and allow access to documentation and sites as required to assess performance against this policy.

Aim & Objectives

The aim of this policy is to promote understanding and awareness of employment laws and ethical standards. By detailing our labour standards to all parts of our supply chain we hope to develop better ethical standards and to motivate suppliers to comply with them. This standard will be required from all potential suppliers in future. To support this aim Malosa has developed the following Labour Standards objectives:

- Compliance with the procedures in the Malosa staff handbook to ensure full compliance with relevant UK & European Employment law throughout 2017.
- Ensure that relevant staff are competent with handling the LSAS by the end of 2017.
- Ensure that Tier 1 suppliers, recorded on LSAS Risk Assessment document, have full compliance with the Malosa Ethical Trading Policy by the end of 2017.
- Encourage parties in our supply chain to develop their own labour standards system and provide help and support to allow them to do this by the end of 2017.



Scope

This policy applies to the devices supplied to the UK National Health Service (NHS) under the following Framework Agreement:

Framework Agreement reference FAG15896

Official Journal of the European Union reference: 2015/S 006-006246

- Ophthalmic Packs
- Single-use Surgical Instruments
- Ophthalmic Accessories & Consumables

Scale

Malosa is committed to implement this policy which is appropriate in nature and scale to the organisation and in accordance with our status as a SME as defined by European Union (EU) law.

Management Representative

The Labour Standards Assurance System (LSAS) will be driven by Malosa Managing Director Gary Loran. The Management Representative assigned the responsibility of implementing the LSAS within the UK is the Quality Manager, Mark Booth who will be assisted by Sophie Sherwell, HR Manager and Valerie Crosby. The responsibilities of the Management Representative and the nominated team are to:

- Develop procedures to meet policy requirements.
- Communicate labour standards issues to the senior management team.
- Liaise with the supply chain to undertake labour standards status reviews.
- Systematically review and continually improve the LSAS.
- Implement training for staff involved with LSAS.

The Management Representative shall liaise with the Managing Director to develop the LSAS and present any developments at regular intervals during Senior Management Team meetings.

Roles and Responsibilities

Given the size of the company and number of companies in its supply chain, it is adequate for the Quality Manager to act as the Management representative responsible for the LSAS. The Quality Manager shall liaise with the Managing Director to develop the LSAS and present developments to the senior management team at appropriate intervals.

Legal Requirements

Malosa is committed to remain up to date with changes to relevant employment legislation through its HR department.

Relevant employment legislation with regards to Malosa direct operations is outlined in the employee contracts and staff handbook issued to all employees.

Objectives, Targets and Programmes

Malosa is committed to developing a Corrective Action Plan (CAP) following each Labour Standards Status review. CAP's are reviewed by senior management, in line with the requirements documented in the Quality Manual, to determine whether the company is on target to reach their objectives and to ensure these objectives are still appropriate. This



activity also ensures that all relevant personnel are kept up to date with the development of the LSAS programme.

Competence, Training and Awareness

Malosa is committed to the training of relevant staff to be competent with handling the LSAS. Relevant staff for Malosa are those involved in procurement and direct operations. LSAS competency and training requirements are determined by the Malosa HR Manager. Staff in roles identified as having influence on labour standards assurance will be:

- Competent in the Malosa Ethical Trading Policy and the LSAS requirements.
- Understand of how business operations with knowledge of the supply chain.
- Authorised to contact suppliers and build relationships with them.

Communications

The LSAS is embedded in the Quality Management System. Malosa records and monitors complaints, allegations or alerts relating to LSAS.

Operational Control

For the direct operation of the company, the Employee Handbook documents the procedures involved with controlling the labour standards of the company and addressing any risks or breaches of this policy that may be posed. It is the responsibility of the HR Manager to ensure that the current applicable labour standards are being referenced.

Critical Control Points

Critical Control Points (CCP) and the method of control are detailed on Malosa Medical Social Accountability Critical Control Points record (LSASCCP). The record is stored within the LSAS File Folder which is available in the Quality Department, Ashday Works Business Park, Elland Road, Elland, HX5 9JB.

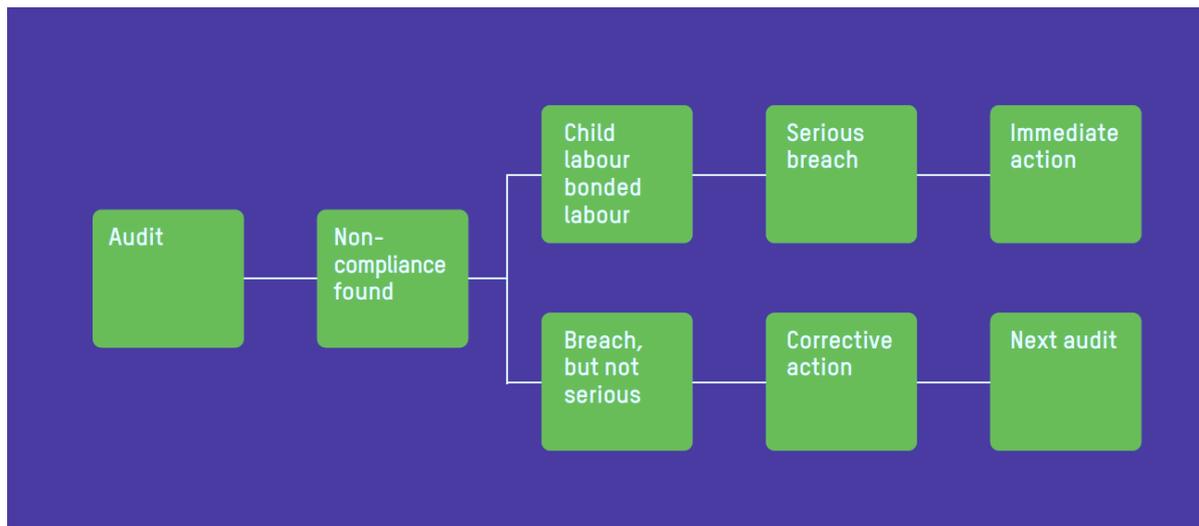
Supply Chain Management

Malosa is committed to monitoring and maintaining the labour standards in the company's supply chain through the distribution and communication of the company's Ethical Trading Policy.

New Tier 1 suppliers must meet initial approval criteria which outline the standards the supplier is expected to maintain as part of their contract. These standards comply fully with those required by the LSAS.

Reviews shall be undertaken during routine visits to suppliers to ensure they continue to comply fully with the LSAS.

The flow chart below illustrates the process to be followed if a non-conformance is identified during a supplier audit.



Emergency/Critical Issue Response

Malosa have identified aspects of its Ethical Trading Policy that it considers of importance for meeting minimum levels of labour standards. Section 1 Policy, Section 4 Legal & Other Requirements, and Section 9 Documentation & Records, are regarded by Senior Management of Malosa as statements that justify emergency response.

Emergency response comprises a request for written Corrective Action Plan (CAP) within 14 days that is approved by all parties involved. Should this CAP be deemed unacceptable then the process of securing an alternative supplier of the product shall be implemented within 60 days of the initial breach of the company’s Ethical Trading Policy.

Management Review

The LSAS programme and progress against LSAS objectives is formally reviewed by the Senior Management Team during the Annual Management Review.