

MEDICAL DEVICES TECHNOLOGY INTERNATIONAL LIMITED LABOUR STANDARDS ASSURANCE SYSTEM POLICY

Medical Devices Technology International Limited (MDTi) manufactures and supplies a range of medical devices throughout the world. MDTi is committed to upholding an ethical labour policy in-line with its legal and moral obligations. The standards are maintained within the Company and the Suppliers within the Company's supply chain.

The Company acknowledges its obligations towards its customers, employees and the communities in which it works, and has decided to document its policy in relation to labour standards and for this document to be approved by senior management; specifically, by the Chief Executive.

MDTi's Management define this policy as relevant to the organisation itself, its contractors, sub-contractors, suppliers and other parties engaged through the supply chain.

Scope of Policy

MDTi applies this policy to all its products and in particular to those products supplied into the NHS via the following Framework Agreement: -

Urology, Bowel and Faecal Management Products framework (OJEU Reference 2015/S 144-265680) Reference No: FAG000016140

Nature and Scale

The Company seeks to implement a policy which is appropriate in nature and scale to the Company and in line with its status, as defined by EU law, as an SME.

LABOUR STANDARDS POLICY

1. Introduction

As a manufacturer of Healthcare Products, MDTi recognize our obligation to provide our customers with high quality, professional goods and services at a competitive price whilst ensuring that at no point is any person in any part of the supply chain is exploited or treated in a way that breaks relevant employment legislation. We are fully aware of the responsibilities we bear to all parties involved in each of the stages involved in producing our products and have such developed this policy to outline the standards that we, and ultimately all stakeholders involved with the business,

should seek to adhere to. MDTi shall show a preference, where appropriate, to suppliers with higher labour standards.

2. Aims

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 by motivating our suppliers to adhere to it. It also describes the standard required of potential future suppliers. MDTi's Labour Standards objectives are as follows:

- To maintain and ensure an ethical company that complies with the ETI Base Code
- KEY Suppliers, as denoted by our Quality Procedure, should have full compliance with the Ethical Trading Initiative (ETI) Base Code by December 2018
- All suppliers should have compliance with at least 70% of the ETI Base Code, which must include the sections of the code that are deemed to be appropriate for Emergency Response as outlined in Section 3.10, by December 2019
- All suppliers should fully comply with the ETI Base Code by December 2018
- Encourage parties in our supply chain to develop their own labour standards system and provide help and support to allow them to do so.

3. Policy Statement

MDTi's policy in relation to labour standards as relevant to the organisation itself, contractors, subcontractors, suppliers and any other parties engaged through the supply chain is as follows:

- We shall comply to all Employment Laws relevant to our business,
- We comply to the Health and Safety Act 1974,
- We comply with all other Employment legislation,
- Our compliance with the above is kept up to date through continuous monitoring,
- We will work towards the ETI Base Code. This demonstrates compliance with the principles of the United Nations Global Compact, the UN Universal Declaration of Human Rights as well as the 1998 International Labour Organisation Declaration on Fundamental Principles and Rights at Work, in accordance with international, national and local law and practice
- We shall encourage all suppliers and contractors to adhere to the Ethical Trading Initiative as part of their respective contracts

3.1 Management Representative

The management representative assigned with the responsibility of implementing an effective Labour Standards Assurance System (LSAS) is Martin Levermore MBE Chief Executive. The responsibilities of the Management Representative are as follows:

- To develop procedures to meet policy requirements
- To communicate labour standards issues to senior management and all staff
- To oversee liaison with companies in the supply chain and to delegate an appropriate individual the undertaking of labour standard status reviews

- To set objectives and targets for labour standards assurance with plans for training, auditing and required action
- To oversee liaison with companies in the supply chain to implement a plan of action to meet objectives
- To regularly review and improve the Labour Standards policy
- To direct training for staff involved with the LSAS

3.2 Roles and Responsibilities

Given the size of the company and the number of companies in the supply chain, it is adequate for the Chief Executive to undertake the main responsibility of the LSAS. The Chief Executive shall develop the LSAS and present any developments at regular intervals to senior management. All staff will be involved with the LSAS and this shall be incorporated into yearly personnel reviews.

Resources relating to the LSAS will be available to all staff through the company's internal servers.

3.3 Labour Standards Status Review

MDTi's is committed to undertaking a comprehensive Labour Standards Status Review; when contracting a new supplier and at regular routine visits to suppliers, to ensure that labour standards throughout our supply chain are satisfactory and continually improving. We recognize that if any contractor or sub-contractor were found to be using unethical or illegal labour programs, this would have a profound impact on the reputation and integrity of MDTi and the health system in general. The procedure for conducting a Labour Standards Review can be found in Company's Quality Management System (QMS). The timescale of the Labour Standards Status Review is subject to change, given the findings from previous reviews, as deemed appropriate by senior management during an Annual Quality Review (AQR).

3.4 Legal Requirements

MDTi's commit to remain up to date with changes to relevant employment legislation through the use of an external information sources. Relevant employment legislation with regards to MDTi's direct operations is outlined in the Company's procedures and is signed by all employees once read and understood.

3.5 Objectives, Targets and Programmes

MDTi's commit to developing a Corrective Action Plan (CAP) as part of the Improvement Request form (IR) following each Labour Standards Status Review. The IR/CAP will be reviewed by senior management during the AQR, in line with the Quality Management System, to determine whether the company is on target to reach their objectives and to ensure these objectives are still appropriate. This will ensure that all relevant personnel will be kept up to date with the development of the LSAS programme.

3.6 Competence, Training and Awareness

MDTi commit to the training of all staff in order to be competent with handling the labour standards programme. All staff for MDTi are those involved in procurement, new product development and customer management. Persons involved with the LSAS should:

- Have a good understanding of how MDTi operates with knowledge of the supply chain
- Be in a position to contact suppliers and build a relationship with them
- Be trained in the LSAS requirements

Training for the LSAS is implemented as part of MDTi's training checklist, which keeps a record of the training levels of all the staff at the company. Training reviews and development plans for the LSAS will be included as part of MDTi's current training system.

3.7 Communications

Since the LSAS is embedded into the current Quality System, the existing training systems, quality systems and recorded communication will be used to address LSAS issues. We will use the IR system to log and monitor any adverse allegations, complaints or alerts relating to the LSAS.

3.8 Documentation and Records

Documentation and records in relation to the LSAS shall be kept using standard document and record keeping procedures in line with other Quality Documents.

3.9 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. The senior management of MDTi have identified two critical control points for labour standards in the supply chain; Supplier Approval and Supplier Visits.

The critical control points that risk will be RAG rated are:

| No. 1 | Critical Control Point Appointing New Supplier/Contractor | Impact on Labour Inadequate labour standards |
|--------------|--|--|
| 2 | Identifying non- conformance & agreeing corrective actions | Improving labour standards |
| 3 | Amending or increasing Purchase Orders | Increased working hours to satisfy additional requirements |
| 4 | Carrying out Supplier Performance Review | Identified gaps in the supplier's documentation |
| 6 | The company being subject to external verification | Lack of adequate resources |

7 Establishing lower prices for the purchase of goods and services

Employing child labour to achieve lower costs to gain order

3.10 Supply Chain Management

MDTi is commit to monitoring and maintaining the labour standards in the company's supply chain through the distribution and communication of the company's labour standards policies along with the on-going assessment of whether these standards are being met. This will occur using assessments at the control points stipulated in Section 3.8. New suppliers must meet MDTi's initial approval that outlines the standards to which the supplier is expected to maintain as part of their contract. These standards comply fully with those required by the LSAS. Reviews shall be taken at routine visits to suppliers to ensure they continue to comply fully with the LSAS. The findings of supplier visits shall be noted in the following AQR. The Quality Management System details the KEY companies involved with manufacturing MDTi's main products and it is an established Quality Document available to all staff.

3.11 Emergency Response

MDTi have identified aspects of the ETI Base Code that are of particular importance for meeting minimum levels of labour standards. Sections 1.1, 1.2, 4.1 and 9.1 are regarded by Senior Management of MDTi as statements that justify emergency response. Emergency Response comprises a request for a written Corrective Action Plan within 14 days that is approved by all parties involved. Should this Corrective Action plan be deemed unacceptable then resourcing of production from within MDTi's existing supplier base shall be implemented within 30 days of the initial breach of the above minimum labour standards.

3.12 Performance Monitoring and Measurement

MDTi commit to monitoring the performance of the LSAS during the AQR as part of resource management, assessing the progress of the programme against the latest CAP where appropriate and setting relevant targets, in addition to those stipulated in this policy, to ensure the progression of the LSAS against our objectives. Progression of parties in the supply chain shall be measured against the level of compliance with the ETI Base Code.

3.13 Corrective Action

The current IR quality system will be used to document improvements from labour standards audits.

3.14 Management Review

Senior management will formally review the labour standards programme during the AQR

4.0 ETI Base Code

The can be found at:

http://www.ethicaltrade.org/sites/default/files/resources/ETI%20Base%20Code%2C%20English.pdf

| Signed on Behalf of: | Supplier's acknowledgement |
|--|-------------------------------------|
| Medical Devices Technology International Ltd (MDTI) | Name: |
| Name: Martin Levermore MBE Position: Chief Executive Date: 18 th May 2016 | Named Person: Position: Date: |