



Labour Standards Assurance Policy and Management System

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1. Overview

Ortho Solutions UK Limited (OrthoSolutions) is a privately owned UK Company based in Maldon, Essex. The Company's principal activities are as an orthopaedic manufacturer specialising in foot and ankle implants along with orthopaedic surgical consumables used in all anatomies.

Established over 20 years ago, OrthoSolutions has become a leader in the UK foot and ankle market with a unique and wide-ranging implant product portfolio. We strive to offer and develop evidence based clinical solutions in collaboration with specialist foot and ankle surgeons which ultimately provides patients with a better quality of life.

OrthoSolutions is committed to maintaining the highest levels of ethical and business standards to preserve its reputation within the marketplace. This is central to our core values and embedded within our business and expected of every sub-contractor and throughout our supply chain. This is clearly set out within our Corporate and Social Responsibility Policy available at www.orthosol.com

OrthoSolutions will only source products from reputable suppliers in low risk labour markets who maintain appropriate ethical standards for the region in which they operate. We expect our suppliers to maintain and monitor these high standards and will take all reasonable steps to establish they are aligned with ours.

Policy

OrthoSolutions Labour Standards Policy is outlined within this Labour Standards Assurance Policy and Management System (LSAS). It applies to both the internal organisation and its supply chain and is approved by the OrthoSolutions board of directors.

We commit to continual improvement in relation to labour standards with adequate and sufficient resources made available to the LSAS, including time and financial support. This is relevant to OS given its scope of products including a wide range of medical and surgical devices.

Our LSAS policy is communicated to all employees by way of induction and training updates with records retained. All new and existing suppliers are sent a copy of the policy and updated annually. The policy is publicly available via our website www.orthosol.com

The LSAS Policy is reviewed annually and evidence of that review is contained in the minutes of the board's AGM.

OrthoSolutions requires all its suppliers to comply with their national laws along with the principles held within LSAS and the Ethical Trading Initiative

2. Management Representative

The Management Representatives for this Labour Standards Assurance Policy and Management System (LSAS) is a shared responsibility within the following roles:

Board of directors / Quality and Regulatory Officer - Administration and overarching management of LSAS

Head of Operations - Supplier interaction and management

These positions have full responsibility and authority for its establishment, implementation, management and ongoing continual improvement.

Responsibilities include:

- Creating and publishing OrthoSolutions LSAS Policy
- Approving all relevant and related LSAS policies and procedures
- Carrying out a periodic review of the LSAS, typically on an annual basis
- Encourage suppliers and all sub-contractors key to the business, to comply with the principles of the LSAS
- Completing risk assessments to determine the level of risks related to each supplier
- Ensuring any corrective actions raised against a particular supplier are addressed in a timely manner
- Allowing staff sufficient time to progress LSAS issues if required
- Documenting and taking action relating to any concerns relating to labour abuses
- Comply with UK employment law
- To align these tasks and responsibilities wherever possible to our ISO 13485 Quality Management System
- To set objectives and targets for the overall improvement of the LSAS policy
- To communicate the LSAS throughout the organisation
- To carry out training with any staff who may be involved in LSAS and if applicable, other parties
- To comply with all NHS Supply Chain Framework Agreements in relation to LSAS

3. Labour Standards Status Review

This procedure undertakes to identify how labour standards such as the NHS Labour Standards Assurance System and the Ethical Trading Initiative relate to OrthoSolutions and its supply chain.

Labour standards are assessed to ascertain which standards apply to either the Company or our supply chain (suppliers and contractors);

Labour Standard	Country	Status
NHS LSAS Specification	UK	Compliant
NHS Supply Chain Code of Conduct	UK	Compliant
Equality Act 2010	UK	Compliant
Public Interest & Disclosure Act 1998	UK	Compliant
Bribery Act 2010	UK	Compliant
Health & Safety at Work Act 1974	UK	Compliant
Employment Act 2008	UK	Compliant
Ethical Trading Initiative 2014	UK	Compliant

Labour Standards status reviews and supplier performance reviews are carried out as part of the LSAS internal audit process on an annual basis. All results are recorded within our ERP and Company shared drive.

OrthoSolutions minimum Labour Standards;

1. Child Labour

The Company does not engage in or support the use of child labour, defined as labour that:

- Is mentally, physically, socially or morally dangerous and harmful to children.
- Interferes with their schooling by;
Depriving them of the opportunity to attend school
Obliging them to leave school prematurely
Requiring them to attempt to combine school attendance with excessively long and heavy Work
- If young workers are engaged for the purpose of work experience then appropriate checks will be carried out to ensure they are not exposed to any harmful conditions and working day is limited to 8 hours.

Forced and Compulsory Labour

OrthoSolutions shall not engage in or support the use of forced or compulsory labour, or bonded or involuntary prison labour as set out in our Modern Slavery Policy. Employees are free to leave upon reasonable notice.

4. Legal and Other Requirements

This procedure has been established to help ensure applicable/relevant legislative and/or voluntary obligations pertinent to employment, welfare, human rights, ethical procurement, equality, discrimination etc. are either available or accessible to staff, and to maintain OrthoSolutions awareness of those labour standards requirements.

It is also an OrthoSolutions requirement for our Company to comply with all UK employment laws and, to influence our suppliers wherever practicable, that they too need to conform to employment legislation as a requisite to supply OrthoSolutions with goods and/or services.

It is the responsibility of the Quality and Regulatory Officer to periodically review these requirements, to confirm our ongoing compliance. In addition, any future proposed changes in legislation will also be identified during that review, and records retained. It is also the responsibility of the Quality and Regulatory Officer that those identified requirements (listed below) are kept up to date.

The sources used to identify and review applicable legislation typically are as follows:

- Advisory, Conciliation and Arbitration Service HSE (Health and Safety Executive)
- UK Government Employing People Business and Human Rights Resource Centre Ethical Trading Initiative
- International Labour Organisation
- United Nations Global Compact Office of the High Commissioner Business for Social Responsibility
- British Medical Association
- Social Accountability International Global Reporting Initiative Sancroft International
- National Health Service National Archives
- External HR Consultant

Sources;

Advisory, Conciliation and Arbitration Service	www.acas.org.uk
UK Government Employing People	www.gov.uk
Ethical Trading Initiative	www.ethicaltrade.org
United Nations Global Compact	www.unglobalcompact.org
Business for Social Responsibility	www.bsr.org
Social Accountability International	www.sa-intl.org
Sancroft International	www.sancroft.com
National Archives	www.legislation.gov.uk
HSE (Health & Safety Executive)	www.hse.gov.uk
Business & Human Rights Resource	www.business-humanrights.org
International Labour Organisation	www.ilo.org
Office of the High Commissioner	www.ohchr.org
British Medical Association	www.bma.org.uk
Global Reporting Initiative	www.globalreporting.org
National Health Service UK	www.nhs.uk
Information Commissioner's Office	https://ico.org.uk/

This procedure also identifies information on relevant employment and human rights legislation and other requirements as they apply to our direct operations, suppliers and other parties in the supply chain.

Those identified include;

Requirement	OrthoSolutions Policy
ETI Base Code / Modern Slavery 2015	Supply Chain Management Policy
Labour Standards Assurance System / International Bill of Human Rights / ILO	Ethical Policy in addition to the Corporate and Social Responsibility Policy
Health & Safety at Work Act 1974	Health & Safety Policy
Bribery Act 2010	Anti-bribery & Corruption Policy
Environmental Protection Act 1990	Environmental Policy
Equality Act 2010 (amended 2012)	Equal Opportunity / Bullying & Harassment Policy

In addition to the above table, OS also conforms to the current GDPR regulations listed in its Employee Handbook and the NHS Supply Chain Code of Conduct. The control document for our suppliers is the Supplier Evaluation Questionnaire which requires any potential supplier to confirm they comply with their relevant national laws.

These examples are not intended to be exhaustive; however, they do provide a framework to ensure that throughout our supply chain, labour abuses are not acceptable. These documents are available to all OS staff to help them understand, and if relevant to their role, how they might apply them. Related documents and records are in place to support compliance in employees Contract of Employment and Employee Handbook.

5. Objectives, Targets and Programmes

OrthoSolutions has established several objectives and targets which are outlined within our LSAS policy. These objectives shall be maintained by a monitoring programme to ensure they are implemented effectively. The ongoing monitoring shall form part of the Company's internal audit programme which is listed within SOP22-8.

All LSAS objectives, which have been agreed with the board of directors when practicable have a plan of action in place to demonstrate how these targets may be achieved (see following table);

Activity	Objective	Action Plan
LEGAL AND OTHER REQUIREMENTS	The procedure(s) the organisation has in place to: Identify information on relevant employment and human rights legislation and other requirements as they apply to its direct operations, contractors, sub-contractors, suppliers and parties in the supply chain. Communicate this information to staff with responsibility for labour standards assurance	To establish a way of identifying the legal requirements in areas of the supply chain which are known to be of elevated risk and also a way of maintaining a current understanding of relevant employment
OPERATIONAL CONTROL	The processes, procedures and systems the organisation has in place to manage labour standards through its direct operations (including both mitigating the risk of non-compliance and driving improvement). This will include how the organisation manages its critical control points	To document a process for critical control Points, supplier approval and site visits for those suppliers purchasing/manufacturing from high risk countries. And begin to implement them into the business processes.
PERFORMANCE MONITORING AND MEASUREMENT	The procedures the organisation has in place to collect appropriate information in order to monitor and measure performance in relation to: <ul style="list-style-type: none"> • Its stated objectives and targets Compliance with relevant legislation and any other requirements that it subscribes to 	To develop a system that allows us to regularly monitor our compliance to our objectives, targets and relevant legislation. A system that will allow us to identify critical dates and flag action points relating to supplier performance.
	<ul style="list-style-type: none"> • Conformance to planned arrangements for labour standards assurance 	
CORRECTIVE ACTION	The procedures the organisation has established in order to manage actual and potential non-conformities to its own labour standards assurance systems, including corrective and preventative action.	To demonstrate the procedures we have established, and are using, to manage both actual and potential non-conformities to our labour standards assurance systems, including corrective and preventative action and also document action plans to mitigate and manage any risks that may arise. This would build further on the incorporation of risk assessments into the new

Objectives will be reviewed annually (minimum) at both the Quality Management Review and Board Meeting.

6. Roles and Responsibilities

This procedure is also detailed in the Company's Quality Management System;

Responsibilities:

The Quality and Regulatory Officer is to ensure the availability of adequate resources to establish, maintain and continually improve the LSAS through;

- Overall responsibility to ensure objectives are met
- To liaise with suppliers to gather required empirical evidence
- To carry out internal audits, report on the findings and generally advise the board of directors

The LSAS programme shall be communicated across the Company which includes issuing current LSAS related policies. All relevant policies and updates shall be sent to all suppliers in a timely manner. Roles and responsibilities to be reviewed at the annual Management Meeting to ensure best practice.

7. Competence, Training and Awareness

This procedure should be read in-conjunction with our Quality Management System and the Administration of Staff Training procedure.

Training records are recorded for LSAS and in the LSAS induction training file. Initial training and awareness to be conducted throughout the organisation to raise awareness of the required labour standards.

Business Ethics and LSAS is addressed at our annual Company meeting covering;

- Business Ethics Policy
- Initial LSAS awareness
- LSAS Company policies
- Ethical Trading Initiative Base Code
- LSAS Specification
- Objectives and Targets

Acknowledgement of this information will be recorded to confirm employee compliance with the policy. Additional training to gain greater competence will be arranged on a case by case basis dependent on how the staff member is involved or can have an influence on labour standards.

Training Plans for each year will be documented in the LSAS Training Schedule which are reviewed at each LSAS Management Meeting (annually as a minimum). All Staff who are directly involved in the management of LSAS will be reviewed annually in their appraisals with any additional training and development steps identified to ensure compliance and development of the LSAS is maintained.

Once training is completed and approved by a manager it is recorded and signed off by the board of directors.

8. Communications Procedure

This Communications Procedure has been established to ensure effective and appropriate communication is in place both internally and externally in relation to receiving and responding to correspondence from interested parties relating to labour standards. The external communication by OrthoSolutions relates to the sharing of practices and performance of our labour standards for any relevant outside party.

Outside parties could include legislators, regulators, customers, suppliers, enforcement agencies, Certification Bodies; Notified Bodies, Competent Authorities, Local Authorities, Trade Unions, Lobbying Groups and the Department of Employment. Key communication issues shall be reviewed at the Management Review meeting, along with any information from whistle blowers.

We shall receive and respond to allegations, complaints or other alerts about labour standards issues as part of our whistle blowing procedures. Whistle blowing can be reported directly to a Manager, HR or board of directors.

All staff are encouraged to discuss labour standards issues between themselves and with the Management Team with LSAS topics also covered in regular staff questionnaires.

This LSAS Policy will be published on the Company's external web site (www.orthosol.com) as evidence of our labour standards programme.

9. Documentation and Records

The objective of these processes and procedures is to drive continual improvement throughout both the Company and our supply chain.

To demonstrate compliance with the NHS LSAS Specification, this Labour Standards Assurance Policy and Management System has been established. As an integral part of managing these activities OrthoSolutions shall wherever practicable, mitigate the risks of non-compliance.

Our documentation is also used to manage its Critical Control Points (CCP) that could have an impact (positively or negatively) on labour standards. Typically these could include:

N	Critical Control	Impact on Labour	Operational Control
1	Appointing New Supplier	Supplier does not have in place adequate labour standards	Risk Assessment
2	Identifying non-conformance & agreeing corrective action	Potentially improving labour standards	Record on Supplier log
3	Carrying out Supplier Performance Review	Identified gaps in the suppliers documentation which may pose additional risks to labour standards	Supplier Workplace Assessment
4	The company being subject to external verification	Lack of adequate resources to maintain the LSAS	Independent LSAS Certification Body Report of Findings

All related policies and documentation shall be recorded on the Company shared drive under LSAS, and also within the QMS folder. Updates are controlled by our QMS for change control.

10. Operational Control

This operational control process shall also consider the method in which we manage our critical control points.

Within our documentation and records section, critical control points (CCP) have been identified and the associated risks have been listed. These CCP include;

- Appointing New Supplier
- Identifying non-conformance and agreeing corrective actions
- Carrying out Supplier Performance Review
- The Company being subject to external verification

All audit results from LSAS Supplier Questionnaires are recorded in the Supplier Management Tracker.

In addition to the above, other critical control points may be identified during our annual Labour Standards Status Review process.

11. Supply Chain Management

This procedure is detailed and should be read in conjunction with our Quality Assurance Procedures; Purchasing and Supplier Surveillance process.

-) All parties involved in the supply chain are included on the Company's Approved Suppliers List. Information regarding each supplier's labour standards performance is collated utilising our Supplier LSAS Risk Assessment Questionnaire Form
-) Key suppliers are identified from the Approved Suppliers List and transferred to the Supplier Management Tracker
-) Any issues identified as part of the risk assessments or audits will be recorded in the corrective action to highlight action is required
-) Data received from the supply chain is then risk assessed to determine a suppliers' continued suitability
-) If necessary, any issues would be highlighted by the Quality and Regulatory Officer at the Management Review Meetings with a decision reached on further action
-) Where applicable other information shall be sent to our supply chain such as the ETI Base Code and our Bribery and Corruption Policy
-) The country of origin of each supplier is recorded on the Supplier Management Tracker
-) Periodically we reserve the right to request additional evidence of labour standards compliance i.e. requesting a copy of a workers contract of employment
-) During the supplier performance verification, if any non-conformances are identified, the corrective action process will be instigated

12. Emergency and Critical Issue Response

OrthoSolutions shall identify and document responses to significant labour standards issues and risks. The procedure adopted shall be appropriate to the issue identified and also reflect the current risks. This shall be achieved by evaluating any action taken during a periodic review.

Typical significant risks and issues include:

- Migrant workers ostracised and discriminated against
- Dormitories - sub-standard lodgings provided to workers with poor safety and hygiene
- Failure of minimum wage payment - being paid a lower wage than nationals
- Double book keeping - factory workers working long hours or hidden data in separate books
- Unpaid internships - potential for forced labour
- Controlled trade unions - little freedom of collective bargaining
- Corruption - employees paid to turn a blind eye to unsafe practices
- Deterioration in the environment - water pollution amongst others
- Breach in labour laws and standards - non-compliance with LSAS

Dependent on the criticality or significance of the issue, OrthoSolutions will put in place a basic plan for each issue. These plans could also be created as a result of a status review, where a supplier is declared to be manufacturing in a high risk area.

A number of methods to manage escalations could be adopted in the plan including;

1. Any risk identified shall be assessed using Supplier Management Tracker, following this Section of LSAS Emergency and Critical Issue Response
2. Ascertain whether the breach is major or minor (view ETI base code corrective action for clarification). Raise a non-conformance on the Supplier Management Tracker and discuss corrective actions with the supplier. All agreements should be documented and a copy sent to the supplier and logged against their account
3. Commence seeking an alternative supplier if the existing approved supplier does not implement corrective action in a timely manner
4. Inform the suppliers/contractors ISO 9001 Certification Body or its ISO 13485 Notified Body to carry out an unannounced visit relating to the organisation's responsibilities of senior management
5. Notify the relevant national enforcement office to intervene
6. Delist the supplier/contractor from our Approved List of Suppliers

If an existing supplier is at risk of being delisted, the relevant manager shall be informed to check with the board of directors prior to placing any additional orders with that supplier

13. Performance Monitoring and Measurement

Data shall be gathered to monitor and measure our stated objectives and targets against compliance with legislation plus all other requirements to conformance.

The following data shall be subject to review;

- Number of prosecutions
- Number of employee tribunals
- Number of enforcement notices
- Number of non-conformances
- Number of whistle blowers reports
- Number of document changes
- Number of issues documented within the supply chain
- Number of supplier assurance questionnaires returned
- Number of objectives and targets achieved
- Number of conformances
- Number of requests for information relating our labour standards performance
- Number of risk assessments carried out and their results
- Number of labour standards abuses including near misses
- Number of observations for improvement documented during internal and external audits

Internal Audits are carried out annually and the outcome is reviewed as part of the LSAS element of the Management Review Meeting. The manager reports on LSAS performance as part of his Business Ethics update to the board of directors.

It is our policy to ensure continual improvement and to demonstrate this, any observations for improvement will be recorded on the Supplier Management Tracker.

14. Corrective Action

Any correctives actions taken shall be recorded on our Supplier Management Tracker.

Any issues noted relating to our suppliers or other parties will be addressed under Performance Monitoring and Measurement relating to Supply Chain Management. In those situations, corrective actions shall be recorded on the Supplier Management tracker.

As with our QMS, once a corrective and/or preventive action has been agreed, the following time scales and responsibilities shall be defined;

-) Major Non-Conformance: Action - Immediate to One Month (dependent on criticality)
-) Minor Non-Conformance: Action - No more than Three Months
-) Observations for Improvement: Action - Dependent on issue, all outcomes will be recorded

The Company shall wherever practicable identify the root cause of any issues of non-conformities raised.

15. Management Review

The LSAS Management Team will meet quarterly to review our compliance against the policy and assess any areas for development and improvement ensuring its continuing suitability, adequacy and effectiveness.

Minutes of LSAS meetings will be filed in the LSAS folder on the shared and QMS drive.

Minutes of the previous management review meeting shall be reviewed and confirmed as accurate prior to the commencement of the current meeting. Any outstanding issues shall be addressed as required.

The meeting reviews will cover the following topics:

- Labour Standards Policy and the Procurement and Supply Chain Policy
- Confirm the duties of the Management Representative have been accomplished
- Review the status of our labour standards
- Check all legal requirements remain current whilst assessing future legislation
- Monitoring objectives and targets; confirm effective programmes in place
- Review employee's roles and responsibilities; verify adequate resources are available
- Check training, competence and awareness of LSAS, ensure initial training has been effective
- Evaluate internal and external communication, including whistle blowers process
- Assess the documents and records procedure confirm compliance with LSAS requirements
- Review operational control and critical control points
- Assess the management of our supply chain, check Supplier Assurance Questionnaire current
- Review Emergency and Critical Issue Response, check labour issues and risks assessments
- Monitor and Measure our LSAS Performance, check compliance with legislation
- Consider Corrective Action and Preventive Action if applicable
- Review Internal Audit Reports (if applicable), consider other internal checks on system
- Finally confirm continued suitability, adequacy and effectiveness of the LSAS for OrthoSolutions

Outcomes

- Confirmation the board of directors has approved all LSAS related policies
- Confirmation future plans for the LSAS have also been approved by the board of directors
- Creation of meeting minutes for the current LSAS Management Review Meeting
- List agreed action points discussed at the meeting (if any) within the Improvement Log
- Confirm continual improvement of the LSAS is in place.

The board of directors will also report on LSAS as part of a wider Business Ethics review held annually at OrthoSolutions AGM.