

 CREST MEDICAL	QUALITY PROCEDURE	QP 235
	Labour Standards Assurance System Manual	
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1 Document History

Revision	6.02	Originator	Claire Deakin
Rebrand: new Crest Medical Logo			
Revision	6.01	Originator	Claire Deakin
Removal of Draft watermark			
Revision	6.00	Originator	Claire Deakin
<p>Summary of change: LRQA added to <i>Abbreviations</i> section; additional Related Documents (QC 002; QC 003; QC 225; QC 226; QC 228; QC 230; QC 233; QC 234; QC 235; QC 250; QP 101; QP 103; QP 110; QP 114; QP 235); <i>LSAS 1</i> - dates removed, changes to scope; <i>LSAS 2</i> - reference to Head of People added; <i>LSAS 4</i> additional information on Management review and meeting minutes, forms and documents updated in Table no.4; <i>LSAS 5</i> - changes to information on company objectives; <i>LSAS 6</i> - reference to Head of People and Contract Manager; <i>LSAS 7</i> - removal of information pertaining to industry experience; <i>LSAS 8</i> - reference to P3 removed, additional information on Quarterly Management Strategy meeting and Management Review, amendments to employee satisfaction survey dates and outsourcing; <i>LSAS 9</i> - added QP 114; <i>LSAS 10</i> - update to QC/QP information; <i>LSAS 11</i> - remove information on requests for additional evidence; <i>LSAS 12</i> - reference to QP 110; formatting, punctuation and typing errors corrected throughout.</p>			
Revision:	5.01		
Summary of change: Crest Medical Holdings to Crest Medical Limited, add child trafficking, forced labour, slavery statements etc.			
Revision:	5.00		



Summary of Change: Transfer to new template; Removal of the term 'not applicable for Level 1' in contents page; Quality Administrator to Compliance Officer; Removal of names to be replaced with job titles; Removal of Crest Organisational Chart; SOP6 replaced with QM001; Addition of reference to QP 103 Training; Removal of Reference to QF27 in Section 11; Additions of Sections LSAS 9, 13 and 14; Roles and Responsibilities amended and populated in Section 6 and also LSAS .

2 Purpose

The purpose of this procedure is to document Crest Medical Limited (CML) commitment to adhering to Labour Standards Assurance System (LSAS) in accordance with the NHS (National Health Service) LSAS Framework for General Wound Care.

3 Scope

The scope of this procedure is to outline CML's implementation of LSAS Levels 1, 2 and 3 of the NHS LSAS Maturity Matrix (15 Sections)

4 Health & Safety

No Health & Safety specific considerations

5 Definitions and Abbreviations

Term	Definition/Abbreviation
LSAS	Labour Standard Assurance Manual
NHS	National Health Service
CML	Crest Medical Limited
QMS	Quality Management system
ILO	Internal Labour organisation
UN	United Nations
ETI	Ethical Trading initiative
LRQA	Accredited Body (audits)

6 Roles and Responsibilities

Under LSAS-6

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7 Related Documents

Document Number	Document Title
QC 002	Health and Safety Policy
QC 003	Environmental Policy
QC 152	Code of Conduct for Ethical Trading
QC 225	ESG Healthy Impact Statement
QC 226	Equality, Diversity and Inclusion Policy
QC 228	Corporate Social Responsibility and Our Supply Chain
QC 233	LSAS Supplier Assessment Form
QC 234	LSAS Internal Audit Report Form
QC 235	LSAS Supplier Audit Report Form
QC 250	Anti-Bribery and Corruption Policy
QP 101	Management Review
QP 103	Training
QP 110	Non-Conformity and CAPA
QP 114	Control of Records
QP 235	Labour Standards Assurance System Manual
	Data Protection Policy

8 Procedure

In accordance with LSAS Levels 1, 2 and 3 of the NHS LSAS Maturity Matrix, the following 15 sections will outline CML's commitment to adhering to the standard and are as follows:

LSAS 1 - Policy

CML's Labour Standards Assurance System (LSAS) Policy is underpinned in its Code of Conduct for Ethical Trading. It clearly applies to both the internal organisation, and its supply chain.

It is approved by Senior Management.


It commits to continual improvement and sets out 15 core minimum Labour Standards.

Adequate and sufficient resources will be made available to the LSAS, and this manifests in both time and financial backing.

It is undoubtedly appropriate to CML, as its scope includes, but isn't limited to, the following – "Wound Irrigation, Dressings both Advanced and General Wound Care Products"

It is communicated to all employees at induction (*LSAS 2 – Induction Checklist*) and on the HR system, available at: www.myhrsystem.co.uk/hrp/login.asp

All Key Suppliers and contractors were identified and sent a copy of the reviewed and updated policy during July 2023.

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Suppliers and contractors are also required to confirm they have read and understood the policy by providing an email confirmation, and for new suppliers they will be required to agree acceptance of the policy as part of the technical agreement, (LSAS 3).

It will be publicly available and to validate this, it will be posted on the company's web site:

www.crestmedical.co.uk

The Code of Conduct for Ethical Trading (QC 152) along with other supporting policies e.g. QC 228 Social Responsibility and our Supply Chain Policy (LSAS 4) is reviewed at least annually.

CML also requires its suppliers to comply with their national laws and that we comply with the principles held within the LSAS Specification and the base code of the Ethical Trading Initiative (ETI) The organisation also commits to complying with regulatory requirements and this is stated throughout its ISO 13485 Quality Management System.

LSAS 2 - Management Representative

The Management Representative responsible for this Labour Standards Assurance System (LSAS) is the Head of People with the support of the Board of Directors and the Senior Management team.

The Management Representative has full responsibility and authority for its establishment, implementation, maintenance; and ongoing continual improvement.

The Managing Director will review progress and compliance during annual Quality Management reviews with Crest Medical's Responsible Person and Compliance Officer.

They are responsible for reporting the effectiveness of the LSAS throughout the company, (LSAS 6).

Typical duties include:

- Approving all other relevant and related LSAS policies and procedures
- Carrying out a periodic review of the LSAS management system, typically on an annual basis.
- To encourage suppliers, contractors and other parties key to the business, to comply to the principles of the Ethical Trading and/or NHS Labour Standards Assurance System
- Completing risk assessments to determine the level of risks related to each supplier
- Ensuring that any corrective action requests raised against a particular supplier, are addressed in a timely manner
- Allowing the administrative staff sufficient time to progress LSAS issues if required
- Documenting and taking actions relating to any concerns about labour abuses
- To comply with UK employment law
- To review labour standard case law and legislation in relevant countries on a quarterly basis.
- To set objectives and targets for the overall improvement of LSAS
- To communicate the LSAS issues throughout Crest Medical Ltd



- To carry out training with the administration staff who may be involved in the LSAS and if applicable other parties
- To comply with the NHS Supply Chain Framework Agreements (relevant to specific devices)

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 both CML and its supply chain.

Labour Standards are then assessed to ascertain which standards apply to either the company or our supply chain (suppliers and contractors). As a part of this assessment, the views of key interested parties shall also be considered.

Criteria within applicable Labour Standards relating to CML and its suppliers and contractors have been identified which include:

Labour Standard	Country	Status
NHS LSAS Specification	UK	Compliant
NHS Supply Chain Code for Conduct	UK	Compliant
Equality Act 2010	UK	Compliant
Public Interest and Disclosure Act 1998	UK	Compliant
Bribery Act 2010	UK	Compliant
Health and Safety at Work Act 1974	UK	Compliant
Employment Act 2008	UK	Compliant
General Data Protection Regulation (GDPR) and Data Protection Act 2015	UK and EU	Compliant
Ethical Trading Initiative 2014	UK	Compliant

Labour Standard	Country	status
Sancroft Country Profile	China	Compliant
International Labour Organisation Conventions	China	Compliant
UN Universal Declaration of Human Rights 1948	All	Compliant
UN Global Compact Principals	All	Compliant

LSAS 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 our CML awareness of those Labour Standards requirements.

It is also a CML requirement for our company to comply with UK employment laws and to influence our supplier wherever practicable, that they need to conform to employment as a requisite to supply CML with goods and/or services. Our Quarterly Senior Management Review ensures we remain compliant with UK law and territories in which our suppliers operate.

In addition, future/proposed changes in legislation will also be identified during that review, and recorded in meeting minutes. It is also the responsibility of Compliance Department for those identified requirements (listed below) to be kept up to date.

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

Table no. 3

Organisation	Web Site Source
Transparency International	www.transparency.org
Advisory, Conciliation and Arbitration Service	www.acas.org.uk
HSE (Health and Safety Executive)	www.hse.gov.uk
UK Government Employing People	www.gov.uk
Business and Human Rights Resource Centre	www.business-humanrights.org
Ethical Trading Initiative	www.ethicaltrade.org
International Labour Organisation	www.ilo.org
United Nations Global compact	www.unglobalcompact.org
Office of the High Commissioner	www.ochr.org
Business for Social Responsibility	www.bsr.org
British Medical Association	www.bma.org.uk
Social Accountability International	www.sa-intl.org
Global Reporting Initiative	www.globalreporting.org
Sancroft International	www.sancroft.com

National Health Service	www.nhs.uk
National Archives	www.legislation.gov.uk
International labour-related law updates	https://www.lexology.com/


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

Those identified include:

Table no.4

Typical UK Obligations	QP Number	CML QP Document Name
ETI Base Code (and overseas)	QP 102	Supplier Assessment
Labour Standards Assurance System	QP 235	Labour Standards Assurance System Manual
Health and Safety at Work Act 1974	QC 002	Health and Safety Policy
Bribery Act 2010	QC 250	Anti - Bribery and Corruption Policy
Environmental Protection Act 1990	QC 225 QC 003 QC 228	ESG Healthy Impact Statement Environment Policy Corporate Social Responsibility and our supply chain 2018
Equality Act 2010 (as amended 2012)	QC 226	Equality and Diversity Policy
Labour Standards	QC 247	Labour Standards Policy
General Data Protection Regulation (GDPR) and Data Protection Act 2015	HR Portal	Data Protection Policy
Code of Conduct for Ethical Trading	QC 152	Code of Conduct for Ethical Trading

Typical Overseas Obligations	Country
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ILO Conventions	China
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The relevant control document from our suppliers is the QC028, Supplier Assessment Form which requires the respondent to confirm whether they comply with their national laws (LSAS 3).

Other information relevant to human rights that are to be reviewed and considered as necessary include:

Other Key Information

NHS Supply Chain- Supplier Code of Conduct

Sancroft Supply Chain Country Profile – China

Note 1:

These examples are not intended to be exhaustive, however they do provide a good foundation to help ensure that throughout our supply chain, labour abuses are not perpetrated. All of these examples are indeed available to our staff to help them understand, and if relevant to their role, how they might apply to them.

Note 2:

Up to date versions of each requirement can be accessed from the various applicable web sites listed above in table no.3.

Note 3:

In addition, other documents and records may also be in place to support compliance, for example employees Contract of Employment, Employment Handbook and NHS Country Profiles etc.

Note 4:

There are a wide variety of other regulations referenced in table no.4, within the employment sector, which will be addressed if an incident (labour abuse) occurs within our supply chain (suppliers and contractors) and any corrective actions put in place if appropriate.

LSAS 5 - Objectives, Targets and Programmes

CML has established a number of objectives and targets and initially they were enshrined (and therefore documented) within our Code of Conduct for Ethical Trading.

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.

As part of the initial Labour Standards review, which also included our requirement for our supply chain to complete QC 233 LSAS Supplier Assessment Form. The company’s objective is to maintain LSAS Level 3.

Objectives shall be reviewed at the Annual Quality Management Review Meeting.

LSAS 6 - Roles and Responsibilities

The NHS Divisional Director and Head of People shall ensure the availability of adequate resources to establish, maintain and continually improve the LSAS. This shall include the appointment of LRQA as an LSAS advisor and external verifier.

- Overall responsibility to ensure objectives are met.
- To liaise with suppliers to gather required and empirical evidence.
- To carry out internal audits, report on the findings and generally advise the Managing Director.
- Be aware from outside agencies/associations, e.g. British Healthcare Trade Association of labour malpractice/investigations.

The LSAS programme shall be communicated across the company, which includes issuing LSAS relating policies on the company HR system.

Additionally, the relevant policies shall be sent out to all suppliers.

Roles and responsibilities are reviewed at the annual Management Strategy Review Meeting and are as follows:

Role	Responsibility
Divisional Director – NHS	Joint responsibility to ensure objectives are met
Head of People	Joint responsibility to ensure objectives are met
Head of Supplier Relationships – Retail and Overseas	To liaise with suppliers to gather required empirical evidence
Compliance Officer	To carry out / facilitate internal audits and report on their findings and generally advise the Divisional Director – NHS and Managing Director.
Contract Manager	Assisting to ensure compliance with LSAS


LSAS 7 - Competence, Training and Awareness

This procedure should be read in-conjunction with CML’s Training Procedure QP 103.

Initial awareness has been introduced at the induction stage and training is undertaken to staff involved to raise and maintain awareness of the required Labour Standards Assurance System

To be covered within the training:

- Initial LSAS awareness
- LSAS Company policies

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- Ethical Trading Initiative Base Code
- LSAS Specification
- Objectives and targets

Attendance of these training sessions will be included on the annual plan and filed within individuals training records.

Additional training to gain greater competence can be arranged on a case-by-case basis dependent on how the staff member can have an influence on Labour Standards.

Plans for training to be included in the training matrix and recorded in the minutes of the Management Strategy Review meeting.

The management representative will if needed, provide support and advice to the supply chain on the various risks associated with not complying with Labour Standard obligations.

LSAS 8 - Communications

It is CML's responsibility to ensure effective and appropriate communication; receiving and responding to correspondence from interested parties relating to Labour Standards, protecting information from whistle blowers, and the external communication in relation to the practices and performance of our Labour Standards.

Interested parties could include legislators, regulators, customers, suppliers, enforcement agencies, Certification Bodies; Notified Bodies, Competent Authorities, Local Authorities, Trade Unions, Lobbying Groups, Department of Employment, etc.

Key communication issues shall be reviewed at the Quarterly Management Strategy meeting, along with information from Whistle Blowers and Management Review QP 101.

We shall receive and respond to allegations, complaints or other alerts about Labour Standards issues as part of our whistle blowing procedures.

CML aims to foster an environment to open communication where concerns can be expressed in confidence to:

The Managing Director on am@crestmedical.co.uk - email

Public Concern at Work on whistle@pcaw.co.uk – email

CML carries out annual employee satisfaction surveys, with the last being completed in March 2023. We will continue to outsource the employee survey to an external HR consultant to manage the results on our behalf, thus providing employees with complete objectivity.

The Code of Conduct for Ethical Trading shall be published on the company's external web site as evidence of our Labour Standards Assurance System commitment.

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LSAS 9 - Documentation and Records

CML's policies are documented on the HR system, with all procedures and forms stored on a validated system called Isotracker which identifies title, date published and issue number along with an audit trail of previous versions with revision history, retained in line with QP 114 Control of Records.

LSAS 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, critical control points (CCP) have been identified and the associated risks have been listed.

These CCP include:

- Appointing New Supplier/Contractor QC 288
- Identifying non-conformance and agreeing corrective actions QP 110
- Carrying out Supplier Risk Assessment QC 230
- The company being subject to external verification through annual audits

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

The critical control points (CCP) have been identified and associated risks have been listed in the below table.

No.	Critical Control Point	Impact on Labour Standards
1	Appointing new supplier/ approved supplier	Supplier does not have in place adequate labour standards
2	Identifying non- conformance and agreeing on corrective actions	Potentially improving labour standards
3	Carrying out supplier performance reviews	Identified gaps in the supplier's documentation, which may pose additional risks to labour standards
4	The company being subject to external verification	Lack of adequate resources to maintain the LSAS
5	Order amendments	Potential increase of labour demand
6	Recruitment	Recruitment of new personnel
7	Service providers	Subcontractors

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LSAS 11 - Supply Chain Management

This procedure should be read in-conjunction with our Quality Management System, supplier approved list and supplier control procedure.

Those parties that are involved in the supply chain are generally included on the Approved Suppliers List

The Corporate Social Responsibility and our Supply Chain Policy (QC 228) has been communicated to our key suppliers, contractors and other parties. Information has been collected relating to our supplier's Labour Standards performance utilising our Supplier Risk Assessment Form (QC 230). Where required, supplier LSAS audits will be completed using QC 234 LSAS Supplier Audit Report Form. Any issues identified, for example a specific policy has not been sent to CML, will be recorded in the corrective action section of the Supplier's LSAS Matrix Review to highlight the fact that we need to respond to the information gathered.

Key suppliers have been identified from the Approved Suppliers List. Any issues identified as part of assessments or audits will be recorded in CAPA forms (QP 110) to address any issues.

Data received from supply chain is then risk assessed to determine suppliers' continued suitability. If necessary, any issues would be highlighted by the management at management review, with decision reached on further action.


Internal LSAS Audits will take place on an annual basis, using QC 234 LSAS Audit Report Form.

LSAS 12 - Emergency and Critical Issue Response

CML shall identify and document responses to significant Labour Standards issues and risks, in accordance with CML Non-Conformance and CAPA Procedure (QP 110). The procedure adopted shall be appropriate to the issue and also reflect the current risks. This shall be achieved by evaluating any action taken during a periodic review or second party audit.

Typical significant risks and issues include:

- Child trafficking – illegal trading of children for labour.
- Forced labour – work that puts children at risk of death, injury or disease.
- 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 is 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
- Slavery – held against their will and not allowed to leave.

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LSAS 13 - Performance Monitoring and Measurement

Through CML's QMS, the Directors will review performance on an annual basis to ensure its continual focus, relevance and alignment to our legal and ethical requirements

Data shall be gathered to monitor and measure our stated objectives and targets, compliant with legislation and other requirements and conformance to planned arrangements.

LSAS 14 - Corrective Actions

CML have a system for documenting all Corrective Actions, in conjunction with Non-Conformances within the QMS (QP 110).

Dependent on the criticality or significant of the issue, CML will put in place a basic plan for each matter. These plans could also be created as a result of a status review. A number of methods that escalate could be adopted in the basic plan including:

1. Raise a non-conformance report, to require the supplier/contractor to change its working practice
2. Commence seeking alternative supplier if the existing approved supplier does not implement corrective action in a timely manner
3. 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
4. Notify the relevant national enforcement office to intervene
5. Delist the supplier/contractor from our Approved List of Suppliers.

Note 1: Any change in the supply chain may require our Notified Body to approve the change prior to its implementation.


LSAS 15 - Management Strategy Review

The Management Representative shall review the CML Labour Standards Assurance System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. Typically, this would be held at least annually. 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 will review the following topics:

Agenda

- Ethical Labour Standards Policy and the Procurement and Supply Chain Policy
- Confirm that the duties of the Management Representative have been accomplished
- Review the status of our Labour Standards
- Check Legal and Other Requirements remain current; also review future legislation
- Monitoring Objectives and Targets; confirm effective programmes in place
- Review employee's roles and responsibilities; verify adequate resources are available

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- 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 are in place
- 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 CML

Outcomes

1. Confirmation that the Managing Director has approved all LSAS related Policies
2. Confirmation that future plans for the LSAS have also been approved by the Managing Director
3. Creation of Meeting Minutes for the current LSAS Management Review Meeting
4. List Action Points raised at the meeting (if any) in the Improvement Log
5. Confirm Continual Improvement of the LSAS is in place.

9 Appendices

N/A