Supplier Standard

Mölnlycke®

Form ID: 000643, rev.02
Site(s): GLO

Table of Contents

Introduction

1.1 About Mölnlycke

Mölnlycke Health Care AB ('Mölnlycke') is a world-leading medical solutions company that equips healthcare professionals to achieve the best patient, clinical and economic outcomes. The company has a long history of developing solutions that increase hospital efficiency; protecting both patients and health care professionals against surgical infections as well as offering effective wound healing.

As a global company, our intention is to work with our supplier base in a globally uniform way and in a manner that ensures reliable supply, superior quality and sustainable business. For more information, visit www.molnlycke.com.

1.2 Purpose and scope of this Supplier Standard

This Supplier Standard is designed to help Mölnlycke's suppliers understand the importance of providing services, raw materials, components and products that continuously comply with the requirements specified by Mölnlycke. The Supplier Standard describes the minimum requirements that potential and existing suppliers have to be able to meet before delivering services to Mölnlycke. Suppliers must follow this Supplier Standard and partner with Mölnlycke to make improvements that result in both parties becoming more efficient, sustainable and competitive.

The supplier must also comply with all applicable standards, regulations and directives relevant to the products and services supplied. Suppliers must also ensure that all critical product characteristics and requirements are identified and the processes employed are robust, capable and documented. Additional requirements for the product and/or service must be defined and agreed upon.

1.3 Conflict of terms

In the event of any conflict between the provisions of this Supplier Standard and the commercial agreement between Mölnlycke and the supplier, the provisions of the commercial agreement will prevail.

Sustainability

As a world-leading medical solutions company, sustainability is a core part of Mölnlycke's approach and key to the company's continued success. In addition to acting in a socially responsible and ethical way in its own business, Mölnlycke seeks to ensure socially and environmentally responsible practices throughout the supply chain. The company asks its primary suppliers to meet its Supplier Code of Conduct and to apply similar Codes of Conduct among their own partners and suppliers.

2.1 Environment

All suppliers must apply a precautionary approach to environmental challenges by considering the environment when selecting products, activities, technologies and services. This could affect, but is not limited to, factors such as the materials used, end-of-life treatment, energy sources and energy consumption. Suppliers must also strive to minimise greenhouse gas emissions (CO2) from their operations.

Suppliers must reduce, reuse and recycle resources as much as possible. They should strive to use and develop environmentally friendly technology and to conduct their business with as low an impact on the environment and public health as possible.

2.1.1 Environmental Management System

Mölnlycke encourages its suppliers to set specific goals to minimise their impact on the environment and to work to continually reduce their environmental footprint. This could be demonstrated by following a process-based quality system to provide a structure for maintaining environmental improvement.

Suppliers must be prepared to demonstrate their commitment and ability to support and further control their environmental impact as prescribed by ISO 14001, such as through:

- an environmental and/or sustainability policy;
- documented investigations of their current environmental impact, including analyses and prioritisations which can be used as a basis for planning actions to reduce environmental impact identification of all applicable legal requirements;
- defining and documenting responsibilities, and available resources;
- setting goals and actions for continuous improvement; and
- regular management reviews of the Environmental Management System (EMS) and its effectiveness.

2.1.2 Chemical legislation

When possible, the use of chemicals and hazardous substances should be eliminated or kept to an absolute minimum. Suppliers must ensure safe handling, storage and disposal of chemicals or hazardous substances, according to applicable standards and to the laws of the country of origin. Listed below are some examples of chemical legislation:

- Toxic Substances Control Act (TOSCA) (USA)
- Corresponding legislation to REACH and TOSCA in other regions
- Biocide legislation
- Occupational health & safety (hazardous substances) legislation
- Dangerous goods regulations (for transport)
- REACH (Registration, Evaluation, Authorization and Restriction of Chemicals).

Mölnlycke requires suppliers operating within or selling to the EU to take full responsibility for pre-registering, registering, notifying and/or applying for authorisation as and when required. This also applies when customs documents identify Mölnlycke as the importer.

To support Mölnlycke in maintaining compliance to ISO Standards and other regulatory and technical requirements, Mölnlycke occasionally asks its suppliers to provide the following information about their products:

- Material or product composition, including Chemical Abstract Service numbers (CAS numbers) and Safety Data Sheet (SDS).

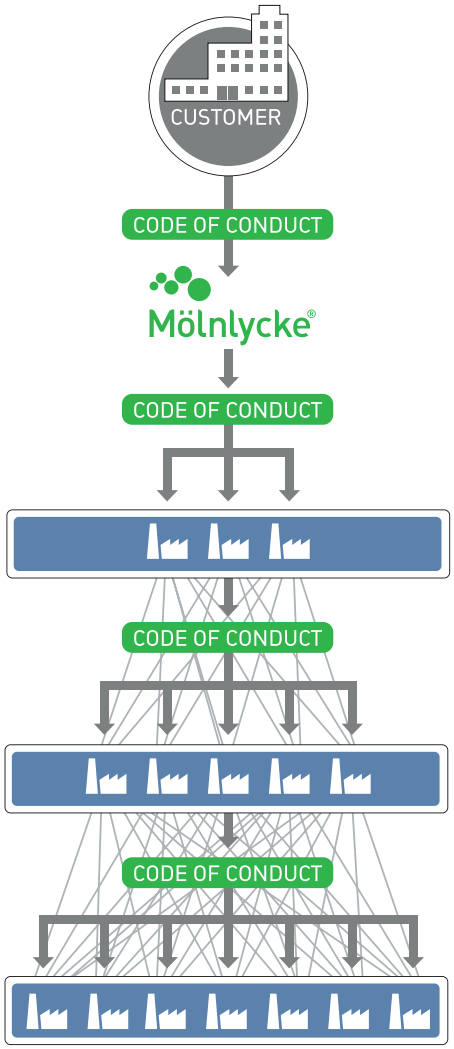
2.2 Supplier Code of Conduct

Mölnlycke demands honesty, integrity and compliance with applicable laws, regulations and standards in all parts of its business, and expects the same from its business partners, including its suppliers and suppliers' suppliers.

As a multinational company and purchaser, Mölnlycke is in a position to impact ethical and social conduct associated with human rights, the workplace and working conditions, gender and race equality, fair competition and anti-bribery and anticorruption in a positive way in its suppliers' factories. The company therefore actively works with suppliers to ensure this.

This Supplier Code of Conduct ('the Code') contains requirements for Mölnlycke's suppliers with regard to applicable laws, standards, human rights, labour rights, health and safety and business integrity. All suppliers are expected to follow the principles and demands set out in the Code. Suppliers are also expected to work proactively to further Mölnlycke's aspirations of continuously improving ambition to be a sustainable business.

Mölnlycke is a signatory of the UN Global Compact and the requirements in the Code are based on its 10 principles. The 10 principles have their foundations in international conventions and declarations such as the Universal Declaration of Human Rights, the ILO's Declaration on Fundamental Principles and Rights at work, the Rio Declaration on Environment and Development as well as the UN Convention Against Corruption.



2.2.1 Compliance with applicable law

Suppliers must always comply with applicable national legislation in the country of operations as a minimum standard, as well as other relevant legislation. If a conflict exists between the Code and national law, national law prevails. Suppliers are also expected to adhere to the 10 principles of the UN Global Compact. Should national law stipulate a lower level of protection, the international standards of the UN Global Compact and its underlying conventions and declarations constitute a minimum level of protection.

2.2.2 Human rights and labour rights

Suppliers must not directly or indirectly engage in promoting, sponsoring or ignoring situations that entail violations of human rights. Suppliers are expected to always respect employees and their rights.

2.2.3 Child labour and young workers

No form of child labour is accepted. A child is defined as any person under the age of 15. But if local minimum age law stipulates a higher age for work or mandatory schooling, the higher age applies.

Additionally, adolescents under the age of 18 must never perform hazardous or strenuous tasks, work during the night or be exposed to anything that could compromise their health, safety or education.

2.2.4 Forced and compulsory labour

Forced labour, involuntary work or unpaid work is never acceptable. Workers must not be required to pay deposits, lodge identity papers or other possessions or have their salary withheld by the employer. They must also be free to leave without penalty after giving reasonable notice.

2.2.5 Fair and equal treatment

Mölnlycke's suppliers must treat all employees with respect and dignity and protect their right to integrity of the person and their right to privacy. Suppliers must never discriminate against employees or job applicants based on gender, age, sexual orientation, race, colour, religion, ethnicity, social origin, disability, political opinion or any other basis. Any form of psychological, physical, sexual or verbal abuse, intimidation, threat or harassment shall never be tolerated.

2.2.6 Health and safety

Suppliers must provide a safe and healthy work environment for all employees. The supplier will
provide all employees with:

- effective health and safety training and instructions on a regular basis;
- appropriate personal protective equipment at the expense of the supplier; and access to clean toilet facilities and drinking water.
- The supplier must also ensure that:any dormitory facilities provided for employees are clean, safe and meet the basic needs of the employees;
- the premises contain adequate, working fire extinguishers, clearly marked exit doors and evacuation plans in the local language in case of fire; and first aid kits are available throughout the facility.

2.2.7 Freedom of association and the right to collective bargaining

Mölnlycke's suppliers must ensure that employees are not prevented from associating freely or negotiating collectively. In situations where the right to freedom of association is restricted under local law, the supplier must allow employees to freely elect their own representative.

2.2.8 Working hours and remuneration

A normal working week must not exceed 48 hours. Overtime must be voluntary and not exceed 12 hours per week, resulting in a working week of maximum 60 hours, (unless stated otherwise in a collective bargaining agreement). All employees are entitled to at least one full day off (24 hours) in every seven days. Employees are entitled to paid sick leave. Wages and other benefits provided by suppliers must be fair and at least equal to the minimum relevant legal and industry standards. Overtime must always be paid at a premium rate.

2.2.9 Business integrity including bribery and corruption

All suppliers must uphold the highest ethical standards when doing business. Suppliers are expected to work actively to prevent bribery and corruption. No supplier, or anyone acting on the behalf of Mölnlycke, may offer or pay a bribe, kickback or other improper payment. Suppliers are also not allowed to provide anything of value that is intended to improperly influence a decision, gain an unfair business advantage, or win business. All suppliers must maintain complete, transparent, and accurate records supporting all transactions undertaken on behalf of or for Mölnlycke.

2.2.10 Compliance with the Code of Conduct

The supplier is responsible for ensuring compliance with the Code as well as for applying and communicating code of conduct requirements to their own suppliers.

If a supplier detects non-compliance with the Code within their operations or supply chain, they must take any necessary action to correct it and report the issue to Mölnlycke.

Mölnlycke conducts supplier compliance risk assessments regularly and reserves the right to carry out on-site audits of its suppliers and subcontractors. The on-site audits may be operated by an independent third party.

If Mölnlycke observes non-compliance with the Code, we will assess whether this can be mitigated and corrected. If this is not possible, the business relationship will be discontinued or a new business relationship will not be initiated.

2.2.11 Reporting concerns

Suspected violation of the Code can be reported via a Mölnlycke employee, or via the Mölnlycke whistle-blowing helpline: https://secure.ethicspoint.eu/domain/media/en/gui/104034/index.html

Employees of suppliers must be able to report issues relating to the Supplier Code of Conduct to their management without risking any negative consequences or retaliation as a result of doing so.

General requirements for all suppliers

3.1 Quality Management System

As a manufacturer of medical devices, it is of vital importance to secure product quality, safety and environmental sensitivity. Mölnlycke requires its suppliers to have established, documented and implemented a process-based quality management system as a means of providing a structure for maintaining effectiveness and initiating continual improvement.

3.2 Audits

Mölnlycke reserves the right to conduct on-site audits of supplier premises, their production and their quality systems. As a result of the regulated environment in which Mölnlycke operates, direct material supplier premises may also be subject to audits by Mölnlycke's Notified Body or the Competent Authority in the member state in which the supplier is based. Such audits may be unannounced.

3.3 Supplier evaluation

Mölnlycke evaluates its suppliers on performance and to detect potential risks. Initial evaluations could take form of questionnaires, visits or audits at the suppliers' premises. Several criteria are considered in supplier questionnaires, such as quality, overall performance and environmental impact. The outcome from each evaluation is summarised in a Supplier Evaluation Report (SER). This states recommendations for continuous improvement, monitoring intervals and the level of risk the supplier is considered to have on Mölnlycke products.

3.4 Change control

Changes need to be verified by Mölnlycke in order to ensure end-product quality and safety. Suppliers must not make changes to their processes or the composition of material(s), product(s) or service(s) without prior written notification to and approval of the change by Mölnlycke unless the supplier is the legal manufacurers. If the Supplier is the legal manufacturer Mölnlycke shall be notified in due time before the change is implemented. Mölnlycke reserves the right to discontinue purchasing activities if it cannot accept the change.

A change is defined as any modification that could potentially affect subsequent processing, product performance, product appearance, product specification as well as any modification that could affect the outcome of the process.

For example, however not limited to:

- Composition of material(s) or product(s): Change of subsupplier or a change in the composition of an already approved material or product
- Process: Any modification to the current processes outside established process parameters
- A modification to equipment or equipment relocation
- Use of alternative sterilisation equipment

3.5 Packaging and labelling

The packaging of goods/items must be designed to protect products from damage, contamination and abnormal deterioration throughout usual transportation and storage. Suppliers should use industry best practice.

Each packaging and pallet must be identified with clearly visible labels on each box, containing the following information:

- Supplier name
- Item description
- Quantity
- Supplier's batch/ Lot number
- Mölnlycke Purchase Order Number (optional)

For distribution services the following documentation must be included:

- Container number (for sea freights)
- Delivery notes (for land transports)
- Airway bill (for air freights)

3.6 Nonconformities

Non-conforming material, products or services might be identified during different phases of processing both at the time of delivery and afterwards. If a nonconformity is identified, a notification will be sent to the supplier.

The Supplier is in turn obliged to notify Mölnlycke without undue delay in case of nonconformities, and suspected nonconformities discovered after the release of the material or product for shipment or after delivery.

Non-conforming material and products will be quarantined. If the material or products are unusable, credit will generally be requested for the unusable material. If value added processing has occurred before the nonconformity was discovered, Mölnlycke may ask for additional compensation for time and materials. Alternatively Mölnlycke may require compensation for product loss if it can be shown that the suppliers' material, product or service was responsible for the loss.

3.6.1 Concessions and rejections

Any nonconformity relating to specification, description, properties, requirements, packaging, labelling or certification may lead to Mölnlycke rejecting material or products.

In the event that Mölnlycke agrees to accept material on concession despite the fact that it is non-conforming, the concession must be completed and approved prior to shipping the material. Non-conforming material or products that arrive without a concession will not be accepted.

The responsible quality representative at the Mölnlycke receiving site initiates concessions or deviation authorisations.

3.6.2 Corrective and preventive actions

Suppliers must prepare a corrective action report and send it to Mölnycke after every nonconformity. Unless otherwise specified, response times to nonconformities are as follows:

Problem awareness, correction and containment: within two days

- Within two working days of receiving the notification, suppliers must confirm to Mölnlycke in writing that the problem has been understood and the problem-solving process is in progress.
- Where the nonconformity may affect other products in production or already produced, suppliers must define and implement an immediate correction to contain and isolate the non-conformity until proper corrective and preventive actions are defined and implemented. Suppliers must also verify the effectiveness of their containment actions.

Root cause, corrective and preventive actions: within 14 working days:

- Suppliers must isolate and verify the root cause of the nonconformity by evaluating each possible cause against the problem description and test data. Suppliers must also isolate and verify the place in the process where the effect of the root cause should have been detected and contained. The response clock starts when the supplier has received all the information, such as photos and returned samples, necessary to conduct the root cause analysis.
- After the root cause is detected, suppliers must determine appropriate corrective and preventive actions to eliminate the root cause. Suppliers must verify that corrective actions will be successful when implemented, without causing undesirable effects.
- A report of the results of the root cause analysis and the status of corrective action implementation must be sent to Mölnlycke within 14 working days from the start of the response clock.
- If corrective and preventive actions cannot be completed within 14 working days, suppliers must submit a detailed plan, linked to the problem-solving form, which describes what actions will be taken and a projected completion date.

Verification on completion

- Once Mölnlycke receives the completed problem-solving form, it will require evidence to clearly show the non-conformity has been corrected.
- Corrective actions for minor non-conformities can typically be verified remotely. But where several minor nonconformities have been observed, or if a major non-conformity is cited, a follow-up site visit may be requested for verification before we can close the action.

3.6.3 Vigilance

When Mölnlycke is the legal manufacturer parties shall cooperate to effect all appropriate remedial actions with respect to any product recall. The Supplier will give full support in order for Mölnlycke to investigate complaints and report to government authorities.

Specific requirements

4.1 Additional requirements for Indirect materials and services

All suppliers of indirect materials and services must have a quality policy and quality procedures and ensure all employees know them. Mölnlycke encourages suppliers to set quality objectives. Certain specific requirements are applicable:

- External laboratories must be in compliance with ISO 9001 and ISO 17025 standards
- Consultants must fulfil the requirements of and perform in accordance with the agreed Statement of Work
- IT and technical service providers must be comply with ISO 9001and ISO 27001 standards where applicable.

4.2 Additional requirements for Direct materials and finished medical devices

Suppliers of direct materials and finished medical devices must have an established Quality Management System fulfilling the requirements set out below:

- Raw materials must be in compliance with ISO 9001 and or ISO 13485 standards.
- Finished medical devices must be in compliance with ISO 13485 standard.
- CE-marked finished medical devices must be certified according to ISO 13485 standard.
- Finished non-medical devices must be certified according to ISO 9001 standard.

Suppliers must establish effective quality assurance procedures to ensure that all delivered materials and devices meet all specifications.

4.2.1 Identification and traceability

Suppliers must establish and maintain procedures that provide positive segregation and traceability of product lots/batches. The scope of segregation and traceability must also be sufficient to support root cause investigations for nonconformities.

Suppliers must gather in-process data regarding quality characteristics and analyse trends. Such data must be made available to Mölnlycke upon request, given reasonable time for compilation. Suppliers should use statistical methods (e.g. process capability studies or target value steering) to control their processes and should perform such studies periodically.

Suppliers are responsible for retaining quality records concerning production batches/lots (e.g. device history records) of at least seven years from the date of generation or, if longer if required by applicable legislation and/or regulations. At a minimum, such information should include:

- Specifications of the goods delivered
- Certificates of analysis
- Traceability records of raw materials or components used for production

Quality records concerning production batches/lots must be made available upon request.

4.2.2 Medical Device Regulation:

Since Mölnlycke operates as a manufacturer, procedure tray producer, importer and distributor of medical devices within the European Union, it has to comply with the Medical Device Regulation (2017/745), known as the MDR.

When Mölnlycke purchases components and finished medical devices from external legal manufacturers for distribution or which are intended to be included into Mölnlycke procedure trays, the following applies:

- If Mölnlycke considers or has reason to believe that a component or finished medical device is not in conformity with the MDR, Mölnlycke will issue a notification to the supplier. Where applicable, Mölnlycke will also inform the Importer, the Supplier's Authorised Representative, the Competent Authority (of the member states where Mölnlycke is established/in which the component or finished medical device has been made available) and the supplier's Notified Body will also be notified, if Mölnlycke considers that the device presents a serious risk.
- Whenever a competent authority asks for it, Mölnlycke has to provide all requested information and documentation necessary to demonstrate the conformity of the component or finished medical device. Mölnlycke therefore expects both the supplier and its Authorised Representative to co-operate to ensure all requested information is available. Mölnlycke will, upon request by a competent authority, provide samples of the component or finished medical device or, where that is impracticable, grant access to the component or finished medical device.
- The supplier is responsible for establishing retention requirements for quality records concerning production batches/lots (device history records) of at least 10 years from the date of generation. Quality records concerning production batches/lots (e.g. product history/sterilisation records) must be made available upon request.
- If Mölnlycke is the Legal Manufacturer of the final product, suppliers must provide Mölnlycke with validation documents for subcontracted processes that can affect the final product quality.

4.2.3 Inspection and testing

For suppliers of direct materials, the supplier agrees to carry out inspection and testing of the quality properties specified by Mölnlycke.

4.2.4 Certificates of conformity and analysis

Mölnlycke may require a certificate of conformity (CoC) or a certificate of analysis (CoA). If required, electronic copies of the certificates must be sent to the Mölnlycke receiving site before the shipment arrives.

Certificates must contain a declaration confirming that applicable materials and products have been manufactured and inspected according to the specifications agreed. The following information must be included for traceability purposes:

- Mölnlycke Item ID Number(s) or applicable product code
- Supplier's lot/Batch number
- Lot/Batch quantity
- Purchase order number
- Last valid specification revision

In addition, the CoA must contain the results of inspection and testing performed according to the applicable specifications and quality properties specified by Mölnlycke.

4.3 Additional requirements for Sterilisation providers

Suppliers which carry out sterilisation must have an established Quality Management System in compliance with the requirements in:

- ISO 11135 (for EtO),
- ISO 11137 (for Radiation),
- ISO 17665 (for Moist Heat),
- ISO 10993-7 Standard, and
- EN 556-1 Standard

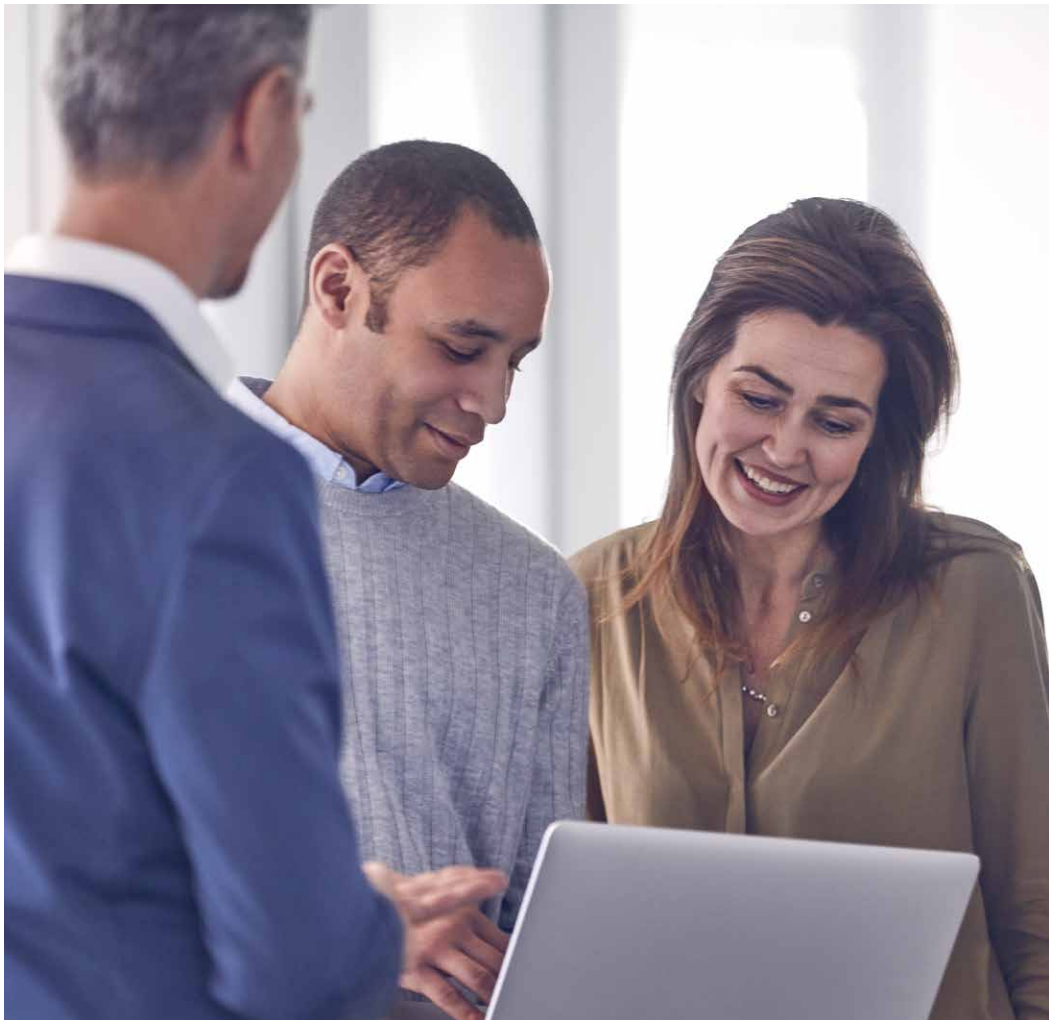
Periodic reviews must be performed and documented in line with applicable sterilisation standards. Mölnlycke requires documented periodic reviews to take place at least annually. The manufacturer of the product is responsible for reviewing the products to be sterilised. The sterilisation supplier is responsible for reviewing the equipment and carrying out requalification.

The supplier must establish effective quality assurance procedures to ensure that each delivery of sterilised products meets all requirements within this Supplier standard. The supplier is responsible for all arrangements that ensure the integrity of the products to be processed. Additional activities, such as storage or special handling, including biological indicators positioning and removal, must be carried out without jeopardising product integrity. The supplier must identify and minimise any activity which could degrade the final quality characteristics and/or properties, ensuring the products meet an acceptable standard and are fully compliant.

Due to the intended use of Mölnlycke's products, bioburden levels and hygienic conditions must be controlled during the production of material(s) or product(s). Questions about sterilisation process changes should be directed to the Mölnlycke Sterilisation owner and to the responsible purchaser within Procurement.

4.3.1 Certificates of sterility

Unless stated otherwise, Mölnlycke requires a certificate of sterility (CoS), prepared by the supplier and issued by the sterilisation service provider for each delivery that has been sterilised.



Electronic copies of the certificates must be sent to the Mölnlycke receiving site before the shipment arrives. This certificate shall confirm the following:

- The equipment used for processing is validated according to valid applicable standards;
- The products processed are known to belong to a validated product family;
- Processing parameters are within defined acceptance range; and
- Detailed documentation of the process is available on request or communicated to Mölnlycke on regular base.

Different sterilisation technologies or service sites require different product documentation and sterilisation parameters to be maintained. The certificate of sterilisation is not a certificate of sterility. For assuring sterility, the certificate of sterilisation shall be completed by relevant manufacturing documentation.

4.3.2 Identification and traceability

Suppliers must establish and maintain procedures that provide positive segregation and traceability of product lots/batches. The scope of segregation and traceability must also be sufficient to support root cause investigations for nonconformities.

Suppliers must gather in-process data regarding quality characteristics and analyse trends. Such data must be made available to Mölnlycke upon request, given reasonable time for compilation. Suppliers should use statistical methods (e.g. process capability studies or target value steering) to control their processes and should perform such studies periodically.

Suppliers are responsible for retaining for quality records concerning production batches/lots (e.g. device history records) of at least seven years from the date of generation – or longer, if required by Mölnlycke.

Quality records concerning production batches/lots must be made available upon request.

Terms and Definitions

Biocide	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
Competent Authority	The government of each Member State of the European Union is required to appoint a Competent Authority responsible for medical devices. The Competent Authority is a body with authority to act on behalf of the government to ensure that the requirements of the Medical Device Directives are transposed into National Law and are applied.
Direct material	All materials or components used in the manufacture of Mölnlycke's end products, which are at some point in contact with or part of the end product. This includes raw materials, standard and specialised components, pharmaceuticals, sub-assemblies, secondary packaging, material for processing and finished medical devices.
Finished medical device	Mölnlycke product delivered to customer either as separate unit or as part of a package.

Indirect material and services	Material and service not directly used in Mölnlycke end products but supporting Mölnlycke's business. Examples include consultants, travel providers, IT services, transportation providers, warehousing, etc.
MDR	Medical Device Regulation.
Parties	Mölnlycke and Supplier collectively.
Problem solving form	Form for corrective and preventive actions.
Process	Set of interrelated or interacting activities which transform inputs into outputs.
Product	Result of a process. There are four generic product categories, as follows; services, software, hardware and processed materials.
Quality records	A document which contains data from an event as a result of performing a procedure or work instruction. Quality records are proof that an organisation is complying with its procedures and policies.
Supplier	A person or an entity providing goods or services to Mölnlycke.
Technical requirements	Document containing agreed technical requirements such as specifications, drawings, packaging instructions, etc.
Working day	A day when the banks are open for general banking business in the country or territory that the products are manufactured in. It is expected that suppliers operate during these working days.

At Mölnlycke, we deliver innovative solutions for managing wounds, improving surgical safety and efficiency, and preventing pressure ulcers. Solutions that help achieve better outcomes and are backed by clinical and health-economics evidence.

In everything we do, we are guided by a single purpose: to help healthcare professionals perform at their best.

And we're committed to proving it every day.

Find out more at www.molnlycke.com

Mölnlycke®