Q-LABEL-015 MEDICINAL PRODUCT QUALITY STANDARD

ABOUT US

The QLabel Quality Label program not only makes it easier for manufacturers to find customers in the market, but also allows consumers to make their purchasing decisions faster and more accurately.

Our organization is a respected organization that has proven to be a leader in its field in the certification, testing, analysis, inspection and audit studies it has shown so far and has gained the trust of both manufacturers and consumers. In all its activities, it maintains its integrity and impartiality by considering the benefit of the society.

The increase and diversification of production and the coexistence of so many types of products in the market naturally confuse consumers.

While consumers demand both quality and high performance products, they also have difficulties in making the right choice among so many products and making the right decisions in their choices.

The QLabel Quality Label, which our organization has developed over the years, is a program designed as a solution to the problems mentioned above.

Title: Q-LABEL

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1. Scope

This standarddefines quality, resilience, deformation, human and environmental health conditions and documentation for medical products.

The Q-Label label registers that the quality conditions of the products are produced according to international Q-Label conditions.

2. Application and Q-Label Label Process

2.1 Organization, Q-Label label reference steps are as follows:

- Application from www.qlabel.org site,
- Approval of Q-Label label license,
- Product testing *
- Q-Label field inspection after product approval
- Q-Label label usage confirmation
- Q-Label etiketinin kullanılması

*The laboratory where the product test will be performed must be authorized from ISO 17025 accreditation or approved by Q-Label.

Q-Label Label Testleri ;

- Chemical Test
- Performance Test,
- Physical Test,
- Endurance Test,
- Quality Test,
- Environment and Human Health Test,

The specified tests may vary according to the products and these tests are carried out according to ISO standards.

Note: Please contact Q-Label for detailed test information.

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2.2 Reference Review

Queue No.	Topic	Mark If Appropriate
1.	Make sure the product is suitable for Q-LABEL	
2.	Contact the competent authority on Q-Label	
3.	Complete application from www.qlabel.org site	
4.	Complete membership in www.qlabel.org site	
5.	Approve license agreement for Q-Label label	
6.	Prepare a technical file for the product with Q-Label label demand	
7.	Upload the technical file required for the Q-Label label to the system	
8.	Send product to relevant lab for Q-Label label	
9.	Q-Label saha denetimi	

2.3 Product Coverage

Allof its medical products fall under Q-Label.

Example : Stretcher, mask, medical equipment, vaccine, etc.

2.4 Certification Period

The Q-Label certification period is 5 years and controls are provided as in the table below.

Audit Period	
First Application	Certification Control
12 Months Later	1.Intermediate Control
24 Months Later	2.Intermediate Control
36 Months Later	3.Intermediate Control
48 Months Later	4.Intermediate Control

*In the annual inspections, samples are taken from the organization and the necessary tests related to the product are carried out in the approved laboratory.

Note: Q-Label mayalso perform audits outside of the above audit periods when you request it.

2.5 Technical File

The organization should prepare the following documents regarding the product to which it will use the Q-Label label:

1. Product content
2. Terms of use
3. Technical content
4. Raw Material Reports
5. Statement*

*The declaration must commit to product quality, human safety and environmental safety.

3. Q-LABEL Management System

The organization should prepare, implement, maintain and continuously improve the necessary documents in accordance with the requirements of this standard.

3.1 Documentation Management

The organization must provide the necessary documentation for the Q-Label management system and include the following;

- Documents required by the Q-Label standard
- Identification (Document name, preparer, approver, document number, etc.)
- Document compliance must be approved and reviewed in terms of competence.
- Distribution (Documents must be accessed)
- Preservation and Disposal

Note-1: Documents must be approved by senior management in terms of proficiency.

Note-2: Records min. must be stored for 5 years.

3.2 Q-Label Policy

The organization must establish, announce and maintain a Q-Label policy.

Policy:

- Compliance with Q-Label requirements and continuous improvement
- Compliance with legal requirements
- Compliance with OHS and Environmental conditions

Note-1: The policy should be announced to the relevant stakeholders.

Note-2: The policy must be approved by senior management.

3.3 Duty Powers and Responsibilities

Tasks, responsibilities should be determined, communicated and documented for the Q-Label processes within the organization. Employees should take full responsibility.

Note -1: Powers and responsibilities must ensure compliance with the requirements of the Q-Label standard.

3.4 Assignment Letter

The organization must identify a staff member for monitoring the Q-Label standard, continuous improvement, implementation and continuity.

Note-1: The personnel to be determined cannot be a person from the senior management.

3.5 Education

Employees should be made aware of the following:

- Regarding Q-Label standard activities,
- Regarding OHS conditions,
- About Q-Label policy

Note-1: Trainings should be planned regularly and employees should be given these trainings.

Note-2: Trainings given to employees should be recorded and evaluated.

Note-3: Education records should be stored according to article 3.1.

3.6 Internal Audit

The organization should conduct internal audits at planned intervals to determine the status of the Q-LABEL management system regarding:

a) whether it complies with:

1) the conditions for the organization's own Q-LABEL management system, including the Q-LABEL policy,

2) the conditions of this standard, whether it is applied effectively and whether it is maintained.

Internal Audit Program;

a) plan, create and maintain an audit program/programs, taking into account the importance of related processes, including frequency, methods, responsibilities, consultation, planning conditions and reporting, and the results of previous audits,

b) determine the criteria and scope of the examination for each examination,

c) select the auditors and carry out the examinations in order to ensure the objectivity and impartiality of the audit process,

d) ensure that the results of the audit are reported to the relevant management; ensure that the results of the relevant audit are reported to employees, employee representatives and other interested parties, if any, where they are located,

e) take action to address nonconformity,

f) as proof of the examination program and the results of the audit.

Note – 1: The frequency of internal examination should be performed at least once a year.

Note – 2: Internal trigger adequacy should be determined according to ISO 19011.

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3.7 Improper Process

If the products labeled Q-Label are not suitable, the organization should start to implement the necessary processes and keep them as documented registration.

The inappropriate process is applied if:

- Using different products instead of Q-Label products
- Misuse of the Q-Label label
- Inappropriate product entry

Note-1: Interested parties should be notified within 3 working days in improper product processes.

Note-2: Inappropriate products should not be destroyed without the approval of the certification body.

3.8 Corrective Action

When an impropriety occurs, the organization:

a) intervene immediately in nonconformity as appropriate from:

1) take action to control and correct it;

2) must fight the consequences;

b) evaluate the need for action to eliminate the causes/causes of nonconformity so that it does not reappe up or occur there through;

1) review of nonconformity;

2) determination of the causes of nonconformity;

3) determine whether similar nonconformities exist or are likely to occur;

c) take all necessary actions;

d) review the effectiveness of the corrective action;

e) make changes to the anti-bribery management system if necessary.

Corrective activities should be in accordance with the effects of nonconformity encountered.

The organization must retain information written as proof of the following:

— the nature of the nonconformity and the actions taken afterwards;

— the results of corrective actions.

3.9 Social Responsibility

The organization should pay attention to the following regarding employees in terms of social responsibility:

- There should be no uninsured employees,
- If there are foreign employees, there must be necessary permits,
- There should be no forced labor,
- There should be no discrimination,
- There should be no child laborers,
- Working hours must comply with legal requirements and overtime pay must be paid
- There should be no financial penalty sanctions,

Note-1: Young workers should not work dangerous jobs when employed

3.10 OHS Management System

The organization must implement the minimum ISO 45001:2018 standard and meet the following requirements:

- Occupational Safety Risk Analysis,
- Emergency Action Plan,
- Personnel OHS trainings,
- Drills (Fire, etc.),
- Emergency Exits and Fire extinguishing equipment,
- Personal protective equipment and records required for personnel,
- Media measurements and recordings and
- Work accidents, if any, should be documented and maintained.

Note-1: In case of employing OHS specialists and doctors in accordance with legal requirements, the contract of the relevant personnel

3.11 Complaint Management

The organization should document and record the process regarding complaints of products labeled Q-Label.

Note-1: Interested parties must be returned within 5 working days.

Note-2: Action should be taken within 3 months regarding complaints.

Note-3: Complaint records should be kept in cons by article 3.1.

4. Supply and Storage Management

4.1 Supplier Verification

Verifying Q-Label input products is as follows:

- Control of Q-Label entries
- Records of Q-Label entries
- Supplier information and verification must be provided.

Note-1: The organization must maintain supplier verification records in cons by article 3.1.

4.2 Inappropriate Input

The Organization should take action in accordance with article 3.7 and inform the relevant parties from the improper entry situation. Q-Label max for inappropriate products. It must be informed within 5 working days.

Note-1: Inappropriate entry records must be retained in accordance with article 3.1.

4.3 Storage and Storage

The organization, Q-Label labeled products and other products should be separated from each other and prevented from mixing.

Note-1: Parsing can be provided with barcode, label, separate storage areas, etc.

5. Production and Traceability Management

5.1 Production Planning

The organization should pay attention to the following in its production planning labeled Q-Label:

- The production must be defined as Q-Label labeled.

The organization must create and maintain production records labeled Q-Label.

The organization must take samples and keep them according to the frequency in the table below.

Sample Frequency	Custom
0 – 10,000 Pieces	1 Piece
10,000 – 100,000 Pieces	3 Pieces
100,000 – 1,000,000 Pcs	5 Pieces
1,000,000 surplus	10 pieces
* Samples should be stored min. for 3 years.	

5.2 İzlenebilirlik

The organization must ensure traceability in the input and output processes of products labeled Q - Label.

Note-1: Traceability can be achieved with barcode, lot no.

6. Sales

The organization should pay attention to the following during the sale of products labeled Q-Label:

6.1 Organization name and contact information,

6.2 The name and address of the customer,

6.3 Invoice date,

6.4 Product description,

6.5 Quantity of products sold,

6.6 Our Company's Q-Label label number,

Note-1: The organization may identify this information on an invoice or packing slip.

Note-2: The organization must maintain sales records in cons by article 3.1.

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7. Logo Usage

The organization must define, implement and verify its process regarding Q-Label label use. See Ek-A Logo Usage

Note-1: The organization may not use the Q-Label label except for approved products.

Note-2: The Organization must obtain approval from the certification body and maintain records before using Q-Label ethics.

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EK-A Q-Label Label Logo Usage

The organization may use logos related to the Q-Label label in the following ways (color, visual, etc.) and sizes.

5 cm

5 cm

Note-1: The Q-Label label logo cannot be used with the logo of another standard.

Note-2: The Q-Label label logo cannot be used on non-Q-Label products.

Note-3: The Q-Label label logo can be used in promotional materials.

Note-4: The Q-Label label logo can only be downloaded by logging into the portal from the organization-specific www.qlabel.org site.

Note-5: The Q-Label label logo has a certificate number requirement and logos without a certificate number cannot be used.

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