What else we can offer you

Certifications and registrations on the basis of

- **ISO 13485** Process-oriented, industry-specific standard based on ISO 9001 with further requirements concerning safety and traceability. **Relevant for:** Manufacturers, distributors and service providers in the medical devices sector.
- **MDSAP** With a MDSAP certificate, recognized by the Canadian authorities, evidencing conformity to ISO 13485, manufacturers of medical devices of classes II, III and IV according to the Canadian Medical Devices Regulations (CMDR), can obtain the license for the Canadian Market. **Relevant for:** Manufacturers of medical devices oriented towards the Canadian market.
- **ISO 9001** Globally applied and recognized standard for ensuring the quality of processes and the results to improve the competitiveness factor. **Relevant for:** Every enterprise. The standard has a high level of recognition in healthcare and health-related social systems.
- **Regulation MDR (EU) 2017/745** of the European Council: Prerequisite for placing medical devices on the market in the European Union. **Relevant for:** Manufacturers of higher than class I medical devices.

Further certifications and registrations in close cooperation with the DQS Group

- i. a. ISO 14001, ISO 50001, ISO 45001, ISO 27001, SCC/SCP, AZAV

Training, seminars, workshops
DQS MED ERFA-Club medical devices
Process audits

Contact us
or visit our homepage.

About us

DQS Medizinprodukte GmbH

- Independent and competent management partner for companies of all sizes and in all industries.
- In 1995, established as the DQS center of excellence for medical devices and designated as a notified body (identification number 0297) approved by the ZLG.
- Founded in 2008 as a wholly owned subsidiary of DQS Holding GmbH.
- Currently supervising by over 200 auditors and experts more than 1,600 customers with around 2,800 certified sites.
- Operating in the areas of medical device approvals and certification of management system in the health care markets for more than 25 years.

DQS Group

- More than 80 offices in over 60 countries.
- Approx. 25,000 customers currently representing approximately 65,000 certified sites in over 130 countries in almost all industries.
- Worldwide, approximately 3,000 employees, including around 2,500 auditors and experts.
- Is today one of the world´s largest system certification bodies.
- Other German subsidiaries of DQS Holding GmbH, headquartered in Frankfurt am Main:
  - DQS GmbH
  - DQS CFS GmbH

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Rev.: 06

Simply leveraging Quality.

ISO 15378
GMP-norm for Primary packaging for medical products

Principles and Significance

Since its publication in 2006, the ISO 15378 is gaining increasingly importance. It includes many statutory requirements from the Medicines Act, Pharmaceuticals and Active Agent Manufacturing Ordinance and the Food and Drug Administration (FDA) to manufacturers of medicinal products. Through this set of rules and regulations specific requests to a supplier of primary packaging materials are available, as all relevant requirements to Good Manufacturing Practice (GMP) are included. The ISO 15378 is process-oriented and in addition to industry-specific includes all requirements of ISO 9001 for a quality management system. With its holistic approach of GMP and quality requirements, ISO 15378 corresponds to the state of the technology.
Primary packaging manufacturers must also meet in addition to the ISO 9001 requirements, a number of other criteria, such as inter alia

- batch traceability,
- risk management,
- validation and controlled environmental conditions.

An ISO 15378 certificate enhances the reputation of companies with their customers and towards authorities and provides the following benefits:

- Proof of compliance with statutory regulations and contractual agreements
- Reduction and control of risks
- Presentation of the company´s expertise
- Creation of competitive advantages
- Improvement of the quality capability
- Time and cost savings

The ISO 15378 Certification Procedure

Procedural cycle takes 3 years

INFORMATION
Information meetings to discuss audit objectives, the certification process and the scope of the management system.

OFFER, APPLICATION and CONTRACT
Detailed offer specifying the scope of services and the time schedule in a transparent manner.

PRE-AUDIT (optional)
Auditing of selected areas or processes to improve certification propability.

SYSTEM ANALYSIS
Audit/assessment i.a. of the system documentation, the results of management review/internal audits, determining the time schedule and the details of the system audit on site.

SYSTEM AUDIT
Comprehensive auditing of the management system on site in order to assess the adequacy and efficiency of the management system and to establish conformity to the requirements of applicable standards. Presentation of the audit results/findings during the closing meeting. Required action plans will be agreed as necessary.

SYSTEM EVALUATION
Written report on audit results.

ISSUANCE OF CERTIFICATE
DQS MED assesses the results and decides independently on issuance of the certificate.

1st and 2nd SURVEILLANCE AUDIT
At least once a year, an audit of essential elements of the management system takes place on site.

RE-CERTIFICATION
Before expiration of the certificate, a new comprehensive audit and assessment of the system will take place to ensure conformity to the standard requirements.

New three-year cycle

ISO 15378 – for whom?

The ISO 15378 applies to manufacturers of primary packaging materials which are in direct contact with the drug. The standard covers all common materials used for primary packaging such as glass, rubber, aluminium and plastic. With the ISO 15378, all contract manufacturers of these materials or rather manufacturers, who pack such materials themselves, can secure early a high GMP standard and international acceptance. For suppliers of primary packaging materials of pharmaceutical products, the standard contains all relevant GMP requirements and enables compliance with international, European and national legal regulations.

DQS Medizinprodukte GmbH was not only the first German Certification body which was accredited for this norm but was also involved in the responsible Standard Committee of the DIN.

dqs

This is to certify that the company

Mustermann und Sohn GmbH & CO. KG

Musterstraße 1
47110 Musterhausen
Germany

has implemented and maintains a **Quality Management System** for Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP)

Scope:
Manufacturing, sales, marketing and distribution of innovative and patient focused with drug delivery solutions for the Pharmaceutical industry.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 15378:2018-08
EN ISO 15378:2017
ISO 15378:2017

Certificate registration no.	004711 PPM
Certificate-ID	12345678
Valid from	2021-12-18
Valid until	2024-12-17
Frankfurt am Main	2021-12-18

DAkkS Deutsche Akkreditierungsstelle D-ZM-10074-01-05

DQS Medizinprodukte GmbH