

Attachment 4

Attachment 4 MEDDEV 2.10-2 Rev 1
April 2001

Special Rules of Accreditation for Certification Bodies of Quality Systems

Scope "Sterile Medical Devices"

Inofficial Translation of

*Spezielle Akkreditierungsregeln für Zertifizierungsstellen für Qualitätssicherungssysteme –
Geltungsbereich „Sterile Medizinprodukte“*

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)

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- 4 Resolutions 2, 6, 7, 9 and 11 of the exchange of experiences circle of the bodies notified according to the Medical Devices Act (EK-Med)

1 Scope "Sterile medical devices"

The approval of quality systems has to be conducted in accordance with the provisions of directive 93/42/EEC annexes II, V, VI, taking into account the classification of devices (§ 13 Medical Devices Act (MPG) or 93/42/EEC, Article 9). Active implantable medical devices are to be treated in an analogous way, taking account of directive 90/385/EEC.

The approval of quality systems of manufacturers who sterilize CE-marked medical devices for the purpose of placing them on the market is issued in accordance with 93/42/EEC, article 12 (3) or § 10 (3) MPG.

Conformity Assessment Procedures

Annex Class	III	VII	combined with	IV	V	VI	or	II
I sterile	—	●		(○)	●	(○)		—
Ila	—	●		○	●	○		●
Ilb	●	—		○	●	○		●
III	●	—		○	●	—		●
Art. 12 (3) all classes	—	—		○	●	○		—

● compulsory ○ applicable — not applicable
(○) applicable in theory, but not relevant to practice

2 Accreditation Requirements

In addition to the Accreditation Rules II-A-3, the special accreditation regulations cited in the following apply to certification bodies which approve quality systems for sterile medical devices.

2.1 Certifying Personnel

Certification bodies may only be accredited for this scope if their personnel fulfil the following requirements:

2.1.1 Senior Executive and Deputy of Certification Body

- Successfully completed studies in medicine, natural science or engineering at a university or higher technical college, or equivalent knowledge in special cases.

- A minimum of three years' full-time professional experience with at least two years' work in testing and/or certification activities in testing/calibration laboratories, - inspection or certification bodies in accordance with EN 45 000 or in comparable institutions and in areas related to the applied scope of accreditation
- Knowledge of quality management procedures in the field of testing, surveillance and/or certification, based on practical experience and successful participation in relevant courses

2.1.2 Audit Team

As a rule, the audit team shall comprise at least two persons¹, who together have the following qualifications:

Quality Auditor

Qualification criteria according to ISO 10 011 Part 2, as well as provable knowledge of the relevant EC directives, the Medical Device Act and the related statutory ordinances.

Experts with technological experience

- Successfully completion of studies in medicine, natural science or engineering at a university or higher technical college, or equivalent knowledge and skills in special cases
- A minimum of three years' full-time professional experience with at least two years' work in areas directly related to the production technology to be assessed, or adequate experience in general process engineering

Experts in sterilization

- Successfully completion of studies in medicine, natural science or engineering at a university or higher technical college, or equivalent knowledge in special cases
- Knowledge in the areas of
 - hygiene
 - microbiology and/or
 - sterilization process engineering
- At least three years' professional experience with at least two years' work in areas directly related to the sterilization technology to be assessed²
- as well as
 - special experience and/or training in clean room technology, determination of bioburden, validation of cleaning, disinfection and sterilization processes, and in sterile packaging
 - proof of successful participation in at least one course in the validation of ethylene oxide sterilization and/or sterilization by irradiation and/or sterilization by moist heat according to EN 550, EN 552, EN 554 as well as in requirements for medical devices labelled sterile according to EN 556
 - proof of participation in at least two sterilization validations based on every harmonised standard for which an authorization is requested. As of 1 July

¹ MedDev 1/94: Guidelines for auditing quality systems of medical device manufacturers

² Instead of two years' work in areas directly related to the sterilization technology to be assessed, the following will also be recognised: an appropriate training programme/further education in connection with attendance at at least three sterilization process audits, the validation of which is based on the respective harmonized standard, under the supervision of an appropriately qualified specialist.

1998, the sitting in on validations is to be carried out with one of the testing laboratories accredited for this scope.

2.1.3 "Certifiers"

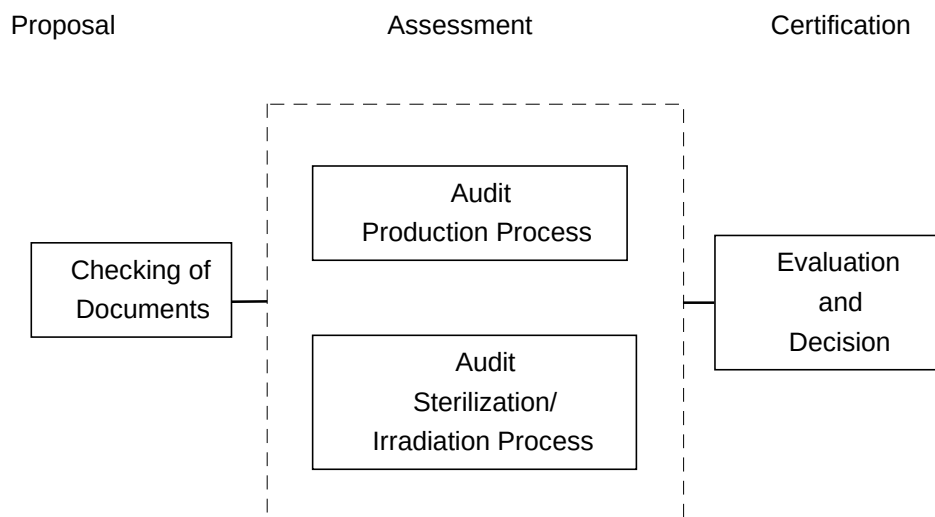
The persons entrusted with in the evaluation must have obtained an adequate qualification in order to evaluate the testing results with highest competence. The independence required must be observed.

2.2 Independence and Impartiality

If persons employed to less than 100% by the certification body are included in the conformity assessment, resolution 9 of the exchange of experiences circle of the bodies designated according to the Medical Devices Act (EK-Med) (4) must be observed.

3 Certification Procedures

Certification bodies must have documented procedures to enable the assessment, certification and surveillance of quality systems to be carried out in accordance with the following requirements:



3.1 Checking of Documents

During document evaluation the following points in particular are to be taken into account

- suitability of the sterilization process for the medical device
- application of EN 550, EN 552 or EN 554 or of a suitable validation procedure deviating from these
- competence of the body which has carried out the validation and routine control of sterilization

As a result of the check of documents crucial points of the audit are to be determined. In particular it has to be decided if subcontractors who sterilize/irradiate medical devices on behalf of the manufacturer must be audited.

Note

Provided the sterilization/irradiation of the medical devices concerned is assigned to a subcontractor, auditing of this subcontractor may be omitted if the notified body receives proof of the following alternative requirements concerning the commissioning:

- a) The validation and routine control of sterilization are carried out by a **testing laboratory accredited for EN 550, EN 552 and EN 554 respectively**.

The requested **summarised commissioning report** – and also, where appropriate, the report on the performance qualification – have been issued by this laboratory.

- b) The sterilization/irradiation plant has a **quality system according to directive 93/42/EEC** approved by a notified body for medical devices that are sterilized with the same equipment.

A summarized commissioning report may be requested if required.

- c) The sterilization/irradiation plant has a certified quality system according to **EN ISO 9001/2 and EN 46001/2** which is under surveillance **by a notified body** or by the inclusion of experts from a notified body. In addition, this notified body **attests** that the commissioning of the sterilization equipment fulfils the requirements according to **EN 550, EN 552 or EN 554**.

A summarised commissioning report may be requested if required.

The physical and – where necessary – microbiological performance qualification remain unaffected by this.

If these conditions are not or only partially fulfilled, an auditing of the sterilization / irradiation plant is to be carried out. This also applies to sterilization/irradiation plants in countries outside Europe.

Deviations from this are to be justified and comprehensibly documented.

3.2 Auditing of manufacturing and sterilization processes

3.2.1 Manufacturing processes

Sterile medical devices must be manufactured and sterilized according to a suitably validated procedure under appropriately monitored conditions.

During production, requirements are to be laid down in accordance with EN 46001/2 among others regarding personal hygiene, monitoring of the surrounding area during manufacture and the cleanliness of the finished products. The results of the check are to be documented.

The audit team checks the conformity of the manufacturing process with the requirements of Annexes II or V of the directive 93/42/EEC or the directive 90/385/EEC, taking account of EN 46001/2, EN 724 or EN ISO 9001/2.

During this check it must also to be considered whether:

- the microbiological-hygienic inspections (e.g. bioburden control, examinations of room air, water, surfaces, sterile work benches, validation of cleaning processes) were carried out expertly and skilfully.

For this, the recommendations in Annex 1 are to be observed.

- suitable sterile packaging and packaging technology was selected for the sterilization procedure applied and whether these ensure that sterility is maintained until the product is used.
- the labelling, when relevant, corresponds to the basic requirements of the directives and, if applicable, EN 980.

- The suitability of the sterile packaging is to be verified taking into account the storing and transport conditions indicated by the manufacturer.
- If no expiry date is given, it must be assumed that the product shelf life is infinite. Accordingly proof should be furnished of the sterile packaging not undergoing any ageing process which could endanger the integrity of the packaging.

3.2.2 Sterilization processes

During the special processes all control parameters are to be recorded. The validation has to be carried out and evaluated by qualified personnel using the required technical methods. The validation report must show by means of appropriate examinations, that the requirements of EN 550, EN 552 or EN 554 are fulfilled or that a comparable validation procedure was applied in order to check the compliance of the product with the specifications in EN 556.

The audit team must check the compliance of the sterilization installation as well as the sterilization documentation kept on site with the details set out in the validation report.

The minimum data needed to evaluate formal compliance with the requirements of EN 550 in a validation report are given in Annex 2.

Minor requirements for validation reports on sterilization with moist heat can be found in the DGKH "Recommendation for the validation and routine surveillance of sterilization processes with moist heat for medical devices" (Annex 3). The annexes 2 and 3 are intended as a recommendation³.

Note

It is appropriate to carry out the specialist check of the validation report before the audit and then to pass on any points that have arisen for the on-site inspection. Where the check of the validation report only takes place during the audit, this must be taken into account by an appropriate period of time in the audit plan.

4 Evaluation and decision-making

The decision on certification is taken on the basis of the documents to be submitted in accordance with the certification procedure by specialist personnel not involved in the audit. (see 2.1.3).

The documents submitted (e.g. check lists, specialist appraisals, audit report) must be sufficiently informative to enable those responsible for the certification as well as the responsible authorities to retrace the relevant circumstances at the time of the audit.

When the decision is taken, it may also be necessary to lay down surveillance measures. This may include not only surveillance audits, but also specific examinations, such as sterility tests, microbiological and physical tests (see resolution 11 of the exchange of experiences circle of the bodies notified according to the Medical Devices Act (EK-Med); Annex 4).

For the approval of quality systems the resolutions 2, 6 and 7 of the exchange of experiences circle of the bodies notified according to the Medical Devices Act (EK-Med); (Annex 4) are to be observed.

³The working group considers specific



the ZLG does not
ation.