# 410.10 Checklist for evaluation of risk management for medical devices

**AZ:** xxxxxx **Device: xxxxxx**

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|---|---|---|---|
| **Ref:** | **xxxxxx** | Date: | |
| **Manufacturer:** | | | |
| **Address:**<br>Street, No.<br>City and ZIP | | | |
| **Auditor:** | Name | **Signature** | |

| | | |
|---|---|---|
| **Device** | Reference | xxxxxx |

## 1.1 Scope

This checklist serves as a specification and a tool for proper auditing of a risk management process (including the correspondent risk analyses).

A risk management audit/evaluation is to be conducted in the following cases:

a. EC design examinations according to the Directive 93/42/EEC Annex II section 4

b. Conformity assessment procedure according to the Directive 93/42/EEC Annex II, V or VI

c. Audits according to EN ISO 13485; in this case the following definition shall be observed

***EN ISO 14971; 2.8: Manufacturer***
*natural or legal person with responsibility for the design, manufacture, packaging, or labelling of the medical device, assembling a system, or adapting a medical device before it is places on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.*

## 2 Evidence

The audit findings must be documented comprehensibly in the audit protocol (DQS notepad "Findings").

The results of risk management auditing are to be listed and substantiated in the audit report, the EC Design examination report or Report for the technical file review.

## 3 Significance of the recognised standards / norms / evidence

## 3.1 Risk management methods

The application of EN ISO 14971 and its (informative) annexes as well as the recognised methods (e.g. FMEA, fault tree analysis) constitutes a presumption that the risk management is, in general, adequate for the considered phase of the product life cycle. Otherwise, the adequacy of the applied risk management must be examined by the auditor and/or the expert based on their competence.

## 3.2 Safety standards for products and processes

The application of the typical harmonised standards for products or applied processes constitutes a presumption, that the requirements to the **design** safety of the products and to the **adequacy of the processes** are, in general, fulfilled. Otherwise, the contents of the risk analysis must be examined by the auditor and/or the expert based on their competence.

## 3.3 Product related evidences to be accepted (procedure according to a. and b.)

EC type examinations according to the Directive 93/42/EEC Annex III for the defined products as evidence of risk analysis for the stage of **design**.

Test mark certificates issued by testing houses on the base of the recognised technical standards as **evidence of the design safety**.

Test records produced by the external testing houses / laboratories as a contracted work are adequate as evi-

dence only for the verifiably examined risks. The test results of the correspondingly accredited laboratories are to be accepted. The external service provider without accreditation may be included in the audit activities, if required.

# 4 Responsibilities and authority

## 4.1 Lead auditor

The lead auditor is responsible for the examination and evaluation of the risk management. He is responsible for the work of the audit team and for the observance of the DQS processes. In case where the lead auditor is not an expert himself, he should accept the evaluation of the sterilization validation by the expert.

## 4.2 Technical expert

The technical expert is responsible for the competent evaluation in content of the aspects of the QM system that are specific for a product or a procedure. Assessment of the required documentation is also his essential task.

# 5 Evaluation of risk management effectiveness

## 5.1 General

The characteristics specific for product or business sector must be taken into account while implementing risk management with respect to:

- the risks of the products themselves
- their application according to the intended use
- knowledge and qualifications of the user

The individual requirements are part of this checklist.

## 5.2 Application of the assessment checklist

The evaluation of the documentation and implementation of a standard's requirement should be documented in the column "Evaluation" in the following way:

1 = fulfilled
2 = partially fulfilled, still acceptable
3 = partially fulfilled, not acceptable
4 = not fulfilled
na = not applicable

Note: The numbering of this checklist corresponds to the numbers of the clauses as printed in EN ISO 14971.

# 6 Further applicable documents

370.2.0 Assessment Guideline

EN ISO 14971

and, where applicable, other standards referenced herein

| No. | Question | Evaluation |
|---|---|---|

## 3 General requirements for risk management (RM)

### 3.1 Risk management process

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|---|---|---|
| 3.1.1 | Is the ongoing process for RM throughout the complete life-cycle defined, documented and maintained? | |
| 3.1.2 | Does the process include the following elements:<br>risk analysis;<br>risk evaluation;<br>risk control;<br>production and post-production information? | |
| 3.1.3 | *Where a documented product realization process exists (EN ISO 13485:2003, clause 7):*<br>Does this process incorporate the appropriate parts of the risk management process? | |

### 3.2 Management responsibilities

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| 3.2.1 | Does the top management provide evidence of its commitment to the RM by ensuring of:<br>the provision of adequate resources;<br>the assignment of the correspondingly qualified personnel? | |
| 3.2.2 | Is there documented policy for determining criteria for risk acceptability? | |
| 3.2.3 | Is it ensured that the following is taken into account as basis for the criteria:<br>applicable national or regional regulations;<br>relevant international standards;<br>available information as the generally accepted state of the art;<br>any known stakeholder concerns? | |
| 3.2.4 | Is the suitability of the RM process reviewed at planned intervals to ensure its continuing effectiveness? | |
| 3.2.5 | Are all decisions and actions taken documented? | |

### 3.3 Qualification of the personnel

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|---|---|---|
| 3.3.1 | Do the personnel have the appropriate knowledge and experience of the medical device and its use, the technologies involved and about RM techniques? | |
| 3.3.2 | Are there appropriate records about that? | |

### 3.4 Risk management plan

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|---|---|---|
| 3.4.1 | Is there a documented risk management plan for the particular medical device considered? | |

| No. | Question | Evaluation |
|---|---|---|
| 3.4.2 | Does the RM plan include:<br>the scope of the planned RM activities, identifying and describing the medical device and its life-cycle phases?<br>assignment of responsibilities and authorities?<br>requirements for review of RM activities?<br>criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of harm cannot be estimated?<br>verification activities?<br>activities related to collection and review of relevant production and post-production information? | |

### 3.5 Risk management file

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|---|---|---|
| 3.5.1 | Is a risk management file established and maintained for the particular medical device considered? | |
| 3.5.2 | Does the RM file provide traceability to the following elements for each identified hazard:<br>the risk analysis?<br>the risk evaluation?<br>the implementation and verification of the risk control measures?<br>the assessment of the acceptability of any residual risks? | |
| 3.5.3 | Are all measures and results of the RM activities recorded? | |

## 4. Risk analysis

### 4.1 Risk analysis process

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|---|---|---|
| 4.1.1 | Are conduction and results of the risk analysis recorded in the RM file? | |
| 4.1.2 | In addition to the records required by clauses 4.2-4.4, does the documentation include at least:<br>a description and identification of the medical device that was analyzed;<br>identification of the person(s) and the organization who carried out the risk analysis;<br>scope and date of the risk analysis? | |

### 4.2 Intended use and identification of characteristics related to the safety of the medical device

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|---|---|---|
| 4.2.1 | Are the intended use and reasonably foreseeable misuse described? | |
| 4.2.2 | Is there a description of those qualitative and quantitative characteristics that could affect safety of the medical device and, where appropriate, their defined limits? | |

### 4.3 Identification of hazards

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|---|---|---|
| 4.3.1 | Is there documentation about known and foreseeable hazards associated with the medical devices in both normal and fault conditions? | |

| No. | Question | Evaluation |
|---|---|---|
| **4.4** | **Estimation of the risk(s) for each hazardous situation** | |
| 4.4.1 | Are the reasonably foreseeable sequences or combinations of events that can result in a hazardous situation considered and the resulting hazardous situation(s) recorded? | |
| 4.4.2 | For each identified hazardous situation, is/are the associated risk(s) estimated using available information or data? | |
| 4.4.3 | *For hazardous situations for which the probability of the occurrence of harm cannot be estimated:*<br>Are the possible consequences listed (for use in risk evaluation and risk control)? | |
| 4.4.4 | Is the system documented that is used for quantitative or qualitative graduation of occurrence probability or severity of consequences? | |
| **5.** | **Risk evaluation** | |
| 5.1 | Does the manufacturer decide using the criteria defined in the risk management plan, for each identified hazardous situation, if risk reduction is required?<br>*If risk reduction is not required, the requirements of the clauses 6.2 to 6.6 do not apply fort his hazardous situation (i.e., proceed to 6.7).* | |
| **6.** | **Risk control** | |
| **6.1** | **Risk reduction** | |
| 6.1.1 | Are risk control activities, as described in 6.2 to 6.7, performed, if necessary? | |
| **6.2** | **Risk control option analysis** | |
| 6.2.1 | Are risk control measure(s) identified and documented that are appropriate for reducing the risk(s) to an acceptable level? | |
| 6.2.2 | Are/is one or more of the following risk control options used (in the priority order as listed):<br>a. inherent safety and design;<br>b. protective measures in the medical device itself or in the manufacturing process;<br>c. information for safety? | |
| 6.2.3 | *If, during risk control option analysis, it is determined that required risk reduction is not practicable:*<br>Is a risk/benefit analysis of the residual risk conducted (see 6.5)? | |
| **6.3** | **Implementation of risk control measure(s)** | |
| 6.2.1 | Are/is the risk control measure(s) selected in 6.2 implemented? | |
| 6.2.2 | Is implementation of each risk control measure verified and recorded? | |
| 6.2.3 | Is the effectiveness of the risk control measure(s) verified and recorded? | |

| No. | Question | Evaluation |
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| **6.4** | **Residual risk evaluation** | |
| 6.4.1 | Is any residual risk evaluated using the criteria defined in the risk management plan? Are the evaluation results recorded? | |
| 6.4.2 | *If the residual risk is not judged acceptable:*<br>Are further risk control measures applied (see 6.2)? | |
| 6.4.3 | *For residual risks that are judged acceptable:*<br>How has it been decided which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those risks? | |
| **6.5** | **Risk/benefit analysis** | |
| 6.5.1 | *If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable:*<br>Is it evidenced (e.g. by review of data and literature), if the medical benefits of the intended use overweigh the residual risk (proceed to 6.6)? | |
| 6.5.2 | *If there is evidence that the medical benefits overweigh the residual risk:*<br>How has it been decided which information for safety is necessary to disclose the residual risk? | |
| 6.5.3 | *If the evidence dies not support the conclusion that the medical benefits overweigh the residual risk:*<br>Is the risk evaluated as not acceptable and is the result of this evaluation recorded? | |
| **6.6** | **Risks arising from risk control measures** | |
| 6.6.1 | Are the effects of the risk control measures reviewed with regard to:<br>the introduction of new hazards or hazardous situations;<br>whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures? | |
| 6.6.2 | Are all new or increased risks managed in accordance with 4.4 to 6.5? | |
| **6.7** | **Completeness of risk control** | |
| 6.7.1 | Is it ensured that the risk(s) from all identified hazardous situations have been considered and recorded? | |
| **7** | **Evaluation of overall residual risk acceptability** | |
| 7.1 | *After all risk control measures have been implemented and verified:*<br>How has it been decided and recorded if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan. | |

| *No.* | *Question* | *Evaluation* |
|---|---|---|
| 7.2 | *If the overall residual risk is not judged acceptable using the established criteria:*<br>Is it evidenced (e.g. by review of data and literature) if the medical benefits of the intended use overweigh the overall residual risk? | |
| 7.3 | *If there is evidence that the medical benefits overweigh the residual risk:*<br>How has it been decided which information for safety is necessary to include in the accompanying documents in order to disclose the overall residual risk? | |
| 7.4 | *If the evidence dies not support the conclusion that the medical benefits overweigh the residual risk:*<br>Is the overall residual risk evaluated as not acceptable and is the result of this evaluation recorded? | |

## 8 Risk management report

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| 8.1 | Is a review of the risk management process carried our prior to release of the medical device for commercial distribution? | |
| 8.2 | Is the responsibility fort his review assigned in the risk management plan to persons having the appropriate authority? | |
| 8.3 | Does this review at least ensure that:<br>the risk management plan has been appropriately implemented;<br>the overall residual risk is acceptable;<br>appropriate methods are in place to obtain relevant production and post-production information? | |

## 9 Production and post-production information

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| 9.1 | Is there a system to collect and review information about the medical device or similar devices in the production and the post-production phases? | |
| 9.2 | Is this system documented? | |
| 9.3 | In the system to collect and review information about the medical device, is the following considered among other things:<br>the mechanisms by which information is collected and processed that is generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device; or<br>new or revised standards? | |
| 9.4 | Is publicly available information about similar medical devices on the market also collected and reviewed? | |
| 9.5 | Is this information evaluated for possible relevance for safety, especially the following:<br>if previously unrecognised hazards or hazardous situations are present; or<br>if the estimated risk(s) arising from a hazardous situation is/are no longer acceptable? | |

| *No.* | *Question* | *Evaluation* |
|---|---|---|
| 9.6 | *If any of the mentioned in 9.5 conditions occur:*<br>is the impact on previously implemented risk management activities evaluated and fed back as input to the risk management process; and<br>is a review of the risk management file for the medical device conducted? | |
| 9.7 | *If there is a potential that the residual risk(s) or its/their acceptability has changed:*<br>Is the impact on previously implemented risk control measures evaluated? | |