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eHealth Suisse

Checklists

Addendum to the guideline for app developers, manufacturers and distributors

Bern, 7 april 2022

ehealthsuisse
Kompetenz- und Koordinationsstelle von Bund und Kantonen
Centre de compétences et de coordination de la Confédération et des cantons
Centro di competenza e di coordinamento di Confederazione e Cantoni

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Additional information and source:

www.e-health-suisse.ch

Purpose and positioning of this document

The aim of these checklists is to provide assistance in individually reviewing the main steps in the development process. The checklists do not guarantee the conformity of the product documentation required to place a medical device on the market.

Contents

A Checklist for risk management

1 Checklist

This checklist is intended for quality and process assurance and should support developers with the main steps related to risk management. This checklist helps to ensure that risk management meets the relevant requirements and that potential gaps are discovered. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
Risk management aspects from ISO 14971						
1	Has a risk management plan been created and does it comply with the requirements from ISO 14971?	☐	☐	☐	CE	☐
2	Has a risk management file been created containing the results from the risk management process (in the form of documents and/or references to the required documents)?	☐	☐	☐	ME	☐
3	Has a risk analysis been performed taking into account the following? - Intended purpose of the medical device - Reasonably foreseeable misuse - Identification of safety-relevant features - Identification of known and foreseeable hazards - Risk assessment for each hazard situation (probability, severity)	☐	☐	☐	CE	☐
4	Have the risks been evaluated and has the evaluation result been documented in the risk management file?	☐	☐	☐	CE	☐
5	Have risk control measures been taken?	☐	☐	☐	CE	☐

Question		Yes	No	n/a	Im-portance	Com-ment
6	Has the implementation of the risk control measures been verified and have the verification results been documented in the risk management file?	☐	☐	☐	CE	☐
7	Have the residual risks been evaluated and have the evaluation results been documented in the risk management file?	☐	☐	☐	ME	☐
8	Has a risk/benefit analysis been performed if the residual risk was considered unacceptable and further risk control measures are not feasible?	☐	☐	☐	CE	☐
9	Have the risks arising due to the risk control measures been analysed?	☐	☐	☐	CE	☐
10	Has the overall residual risk been evaluated based on the criteria stipulated in the risk management plan?	☐	☐	☐	CE	☐
11	Has a risk management report been created that documents the results from the review of the risk management process?	☐	☐	☐	ME	☐
12	Has a system been established for collecting and reviewing information about the medical device or similar products from the manufacturing stage as well as from stages that are further downstream?	☐	☐	☐	ME	☐
Risk management aspects from IEC 62304						
13	Was a risk management process applied in accordance with ISO 14971?	☐	☐	☐	CE	☐
14	In case older software is used in the medical device: Has all feedback about this software been investigated in relation to accidents or near-accidents?	☐	☐	☐	ME	☐
15	In case older software is used in the medical device: Was this software subjected to a risk management process?	☐	☐	☐	ME	☐
16	Does the software development plan define how to implement software risk management?	☐	☐	☐	ME	☐

Question		Yes	No	n/a	Importance	Comment
17	If relevant: Have risk control measures been incorporated into the requirements?	☐	☐	☐	CE	☐
18	If requirements were defined in the course of software development: Has the risk analysis been re-evaluated and updated?	☐	☐	☐	CE	☐
19	Have the necessary risk control boundaries been defined between software components and has it been ensured that the boundaries are effective?	☐	☐	☐	CE	☐
20	Has it been investigated in the risk management process whether there are software components that can contribute to hazardous situations?	☐	☐	☐	CE	☐
21	Have causes that contribute to a hazardous situation been identified and documented in the risk management file?	☐	☐	☐	CE	☐
22	If a failure or unexpected results produced by software of unknown provenance (SOUP) are the reason that the software component contributes to a hazardous situation: Have published lists of anomalies been evaluated for the SOUP version?	☐	☐	☐	ME	☐
23	If a software component can contribute to a hazardous situation: Have risk control measures been defined and documented?	☐	☐	☐	CE	☐
24	If risk control measures are implemented as part of a software component's functionality: - Have the measures been incorporated into the requirements? - Was a safety class assigned to the software component? - Was the software component developed in accordance with IEC 62304?	☐	☐	☐	CE	☐
25	Have the implementations of the risk control measures been verified and has the verification result been documented?	☐	☐	☐	CE	☐

Question		Yes	No	n/a	Im-portance	Com-ment
26	Is the traceability hazardous situation -> software component -> cause -> risk control measure -> verification appropriately documented?	☐	☐	☐	ME	☐
27	If changes were made to the software, has it been analysed whether additional causes were introduced that could contribute to a hazardous situation?	☐	☐	☐	CE	☐
28	If changes were made to the software, has it been analysed whether additional risk control measures are required?	☐	☐	☐	CE	☐
29	If changes were made to the software, has it been analysed whether the changes could disrupt existing risk control measures?	☐	☐	☐	CE	☐
30	Have relevant risk management activities been carried out in response to the analysed changes?	☐	☐	☐	CE	☐
Risk management aspects from IEC 62366						
31	Have the acceptance criteria defined in the usability validation plan been fulfilled?	☐	☐	☐	CE	☐
32	Has safety information used for the purpose of risk reduction been taken into account in the usability process?	☐	☐	☐	CE	☐
33	Have safety-relevant properties been identified with a focus on usability and documented in the usability engineering file?	☐	☐	☐	ME	☐
34	Have usability-relevant hazards that are known or foreseeable been identified and documented in the usability engineering file?	☐	☐	☐	CE	☐

Importance

CE = Critical Error -> The project cannot proceed until the error has been corrected.

ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

B Checklist for configuration management

1 Checklist

This checklist is intended for quality and process assurance and should support developers with the main steps related to configuration management. This checklist helps to ensure that configuration management meets the relevant requirements and that existing gaps are discovered. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
Configuration elements						
1	Is there an overview of the elements and the corresponding descriptions?	☐	☐	☐	ME	☐
2	Are the software configuration elements clearly identified?	☐	☐	☐	CE	☐
3	Are the versions of the software configuration elements clearly identified?	☐	☐	☐	ME	☐
Project environment						
4	Has the project environment been created?	☐	☐	☐	CE	☐
5	Has the directory structure for the workspace been specified?	☐	☐	☐	ME	☐
6	Have the overview and the description of the tools been created?	☐	☐	☐	ME	☐
7	Have the overview and the description of the external components been created?	☐	☐	☐	ME	☐

Question		Yes	No	n/a	Im-portance	Com-ment
Management of configuration elements						
8	Were the structural changes to the project structure made after consulting with the person responsible for the components?	☐	☐	☐	ME	☐
9	Is the management of the configuration elements documented?	☐	☐	☐	ME	☐
Change management						
10	Is the execution of changes documented?	☐	☐	☐	ME	☐
11	Is traceability ensured?	☐	☐	☐	CE	☐
Version management						
12	Is it defined how the builds are versioned?	☐	☐	☐	CE	☐
Backward compatibility						
13	It is defined how the software should handle backward compatibility?	☐	☐	☐	CE	☐
Release						
14	Are the conditions defined that must be fulfilled before the issuance of the release can begin?	☐	☐	☐	CE	☐
15	Is the procedure for issuance of the release defined?	☐	☐	☐	ME	☐
16	Is the software distribution strategy defined?	☐	☐	☐	ME	☐
17	Is the update distribution strategy defined?	☐	☐	☐	ME	☐
18	Is it defined how the software release is to be archived?	☐	☐	☐	ME	☐
19	Is it defined how long the software release must be archived?	☐	☐	☐	ME	☐

Importance

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ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

C Checklist for the definition phase

1 Checklist

This checklist is intended for quality and process assurance and should support developers with the main steps related to the definition phase. This checklist helps to ensure that the definition phase meets the relevant requirements and that potential gaps are discovered. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation. For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
Planning of software development						
1	Has a software development plan (SDP) been created?	☐	☐	☐	CE	☐
2	Are the different software development phases defined in a software development plan (SDP)?	☐	☐	☐	CE	☐
3	Are the deliverables for each phase of software development defined in the SDP?	☐	☐	☐	ME	☐
4	Are milestones defined?	☐	☐	☐	ME	☐
5	Is traceability of the requirements guaranteed for audits and risk control measures?	☐	☐	☐	ME	☐
6	Are acceptance criteria defined for verification of the deliverables?	☐	☐	☐	ME	☐
7	Does the documentation in the SDP correspond to the progress of the project?	☐	☐	☐	ME	☐
8	Are the system requirements referenced in the SDP?	☐	☐	☐	SE	☐

Question		Yes	No	n/a	Importance	Comment
Software requirements						
9	Are the system requirements (including the risk control requirements) implemented in the software requirements?	☐	☐	☐	CE	☐
10	Are the software requirements not mutually contradictory?	☐	☐	☐	CE	☐
11	Are the software requirements formulated to avoid ambiguity?	☐	☐	☐	ME	☐
12	Are the software requirements formulated to enable the definition of test criteria and execution of tests that will determine whether the test criteria are fulfilled?	☐	☐	☐	ME	☐
13	Can the software requirements be clearly identified?	☐	☐	☐	ME	☐
14	Can the software requirements be traced back to system requirements or other sources?	☐	☐	☐	ME	☐
15	Was the risk analysis for the medical device re-evaluated after definition of the software requirements and modified if necessary?	☐	☐	☐	ME	☐
16	Were the system requirements re-evaluated after definition of the software requirements and modified if necessary?	☐	☐	☐	SE	☐

Importance

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ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

D Checklist for the architecture phase

1 Checklist for the architecture phase

This checklist is intended for quality and process assurance and should support developers with the main steps related to the architecture phase. This checklist helps to ensure that the architecture phase meets the relevant requirements and that potential gaps are discovered. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
General information						
1	Has the software architecture been created?	☐	☐	☐	CE	☐
2	Are the system and software requirements implemented along with the architecture?	☐	☐	☐	CE	☐
3	Are the requirements for risk control implemented by the architecture?	☐	☐	☐	CE	☐
4	Are the interfaces supported between the individual software components and between the software components and hardware?	☐	☐	☐	ME	☐
5	Does the architecture support proper operation of all SOUP components?	☐	☐	☐	ME	☐

Importance

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ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

E Checklist for the software release phase

1 Checklist

This checklist is intended for quality and process assurance and should support developers with the main steps related to the release phase. This checklist helps to ensure that the release phase meets the relevant requirements and that potential gaps are discovered. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
General information						
1	Is the software up-to-date (latest version)?	☐	☐	☐	CE	☐
2	Have all errors in the error list been corrected?	☐	☐	☐	CE	☐
3	Are the software anomalies documented and do not lead to critical errors?	☐	☐	☐	CE	☐
4	Has debugging and test code been removed from the software?	☐	☐	☐	ME	☐
5	Backup completed?	☐	☐	☐	CE	☐
6	Have configuration statuses been created that include all components?	☐	☐	☐	CE	☐
7	Has the installation guide been created?	☐	☐	☐	ME	☐
8	Has the risk analysis been performed?	☐	☐	☐	CE	☐
9	Has quality control been performed?	☐	☐	☐	CE	☐
10	Have the copyright, license, QM and legal documents been reviewed?	☐	☐	☐	CE	☐
11	Is the software release documentation ready?	☐	☐	☐	CE	☐

Importance

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ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

F Checklist for data protection and data security

1 Checklist

This checklist is intended for quality and process assurance. It should support developers when examining the necessary measures for compliance with the data protection and data security requirements. To ensure that an adequate security concept has been implemented, this checklist should help during the concept review process. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Working through the checklist helps to guarantee that all relevant measures required to ensure data protection and data security are implemented and that existing gaps are discovered.

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

The following checklist is intended as an orientation guide. It cannot substitute for concrete analysis on a case-by-case basis. It does not claim to be complete. Usage of this checklist is at your own risk. Depending on the situation, it may be advisable to consult a data protection specialist.

		Yes	No	n/a	Importance	Comment
Data protection and data security (under Swiss law)						
1.	Have the app users consented to the processing of their personal data?	☐	☐	☐	CE	☐
2.	If question 1 was answered yes: Was consent given for a specific processing purpose or for multiple specific processing purposes? AND Is the consent - voluntary (given without pressure), - clear (unquestionable) and - explicit (ideally in writing and thus verifiable)?	☐	☐	☐	CE	☐
3.	Are app users informed about the purposes for which the app processes their personal data?	☐	☐	☐	CE	☐
4.	Does the app process only as much data as it needs to fulfil the specified purpose or purposes?	☐	☐	☐	ME	☐

		Yes	No	n/a	Im-portance	Com-ment
5.	Does the app promptly delete data that it no longer needs to fulfil the specified purpose or purposes?	☐	☐	☐	ME	☐
6.	Are the apps designed from a technical and organisational perspective to ensure risk-appropriate data security?	☐	☐	☐	CE	☐
7.	Are users informed about the appropriate point of contact to assert their rights as data subjects?	☐	☐	☐	CE	☐
8.	Are the apps also offered in the EU and is data processed for persons in the EU?	☐	☐	☐	-	☐
9.	If question 8 was answered yes: Have the apps been reviewed for compliance with the EU data protection legislation?	☐	☐	☐	CE	☐

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2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

G Checklist for usability

1 Checklist

This checklist is intended for quality and process assurance and should support developers with the main steps related to usability. This checklist helps to ensure that the product fulfils the requirements for usability. The idea is for the review to be carried out by multiple persons. Both the team's results and the project manager's results are documented (see section 3).

Working through the checklist helps to guarantee that all relevant steps for compliant surveillance are completed and that existing gaps are discovered.

Comments related to individual questions can be marked in the list and inserted at the end of the table.

After the review, the checklist is signed, released and filed away to become part of the technical documentation.

For additional information, consult the guideline.

Question		Yes	No	n/a	Importance	Comment
General information						
1	Has the intended purpose of the software product been determined and documented?	☐	☐	☐	CE	☐
2	Have the user profile and operating environment been determined and documented?	☐	☐	☐	CE	☐
3	Have the following points been determined and documented in the specification for the application? – Intended medical indication – Intended patient group – Body part or tissue type – Intended user profile – Intended usage conditions – Modes of operation	☐	☐	☐	CE	☐
4	Have risk control measures been defined and documented for unacceptable risks?	☐	☐	☐	CE	☐
5	Have the safety-relevant functions been defined and itemised?	☐	☐	☐	CE	☐
6	Have the main operating functions been defined and itemised?	☐	☐	☐	CE	☐

Question		Yes	No	n/a	Importance	Comment
7	Has the usability validation plan been created?	☐	☐	☐	CE	☐
8	Is the design of the user interface documented?	☐	☐	☐	CE	☐
9	Is the usability verification documented?	☐	☐	☐	CE	☐
10	Is the usability validation documented?	☐	☐	☐	CE	☐
11	If training is necessary: Have the training materials been documented?	☐	☐	☐	CE	☐
12	Are the usability requirements for the software product documented as input to the system requirements?	☐	☐	☐	CE	☐
13	Are the usability requirements for the software product defined such that the manufacturer can fulfil these requirements?	☐	☐	☐	CE	☐
Application specifications						
14	Is the application of the software product specified and documented in the usability engineering file?	☐	☐	☐	CE	☐
Frequently used functions						
15	Are the frequently used functions involving user interaction with the software product defined and documented in the usability engineering file?	☐	☐	☐	CE	☐
Identification of hazards and hazardous situations						
16	Have the safety-relevant properties been identified and documented in the usability engineering file?	☐	☐	☐	CE	☐
17	Have the foreseeable hazards, hazardous situations and related severity been identified and documented in the usability engineering file?	☐	☐	☐	CE	☐
Main operating functions						
18	Have the main operating functions been identified and documented in the usability engineering file?	☐	☐	☐	CE	☐
Usability specification						

Question		Yes	No	n/a	Importance	Comment
19	Are testable requirements provided for usability verification in the usability specification?	☐	☐	☐	CE	☐
20	Are testable requirements provided for the main operating functions in the usability specification?	☐	☐	☐	CE	☐
21	Have the usage scenarios been described and documented?	☐	☐	☐	CE	☐
22	Have the requirements for the user interface been described and documented?	☐	☐	☐	CE	☐
23	Have the requirements needed to determine whether the user can easily recognize the main operating functions been described and documented?	☐	☐	☐	CE	☐
Usability validation plan						
24	Is the usability validation plan prepared and up-to-date?	☐	☐	☐	CE	☐
Design and implementation of the user interface						
25	Was the user interface designed and implemented as described in the usability specification?	☐	☐	☐	CE	☐
Usability verification						
26	Has the implementation of the user interface been verified against the requirements in the usability specification?	☐	☐	☐	CE	☐
27	Have the results of this verification been documented in the usability engineering file?	☐	☐	☐	CE	☐
Usability validation						
28	Has the usability of the medical device been validated as described in the validation plan?	☐	☐	☐	CE	☐
29	Have the results of this validation been documented in the usability engineering file?	☐	☐	☐	CE	☐
Accompanying documentation						

Question		Yes	No	n/a	Im-portance	Com-ment
30	Does the accompanying documentation contain a summary of the application specification for the software product?	☐	☐	☐	CE	☐
31	Does the accompanying documentation contain a concise description for the following points (if relevant for usage)? – Functional principle – Significant physical characteristics – Significant performance features – Intended user profile	☐	☐	☐	CE	☐
Training and training materials						
32	If training is required in order for the intended user to safely and effectively use the main operating functions of the software product, is one of the following possibilities created? – Training materials are provided – Access to training materials is ensured – Training is provided	☐	☐	☐	CE	☐
33	If training is required, does the accompanying documentation describe the available possibilities for training and contain suggestions on the duration and frequency of training?	☐	☐	☐	CE	☐
34	If training is required, have the intended purpose and user profile been used as the basis for the training as well as the training materials?	☐	☐	☐	CE	☐

Importance

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ME = Major Error -> Must be addressed, but the next phase may already begin.

SE = Secondary Error -> From a regulatory perspective, there is no reason to halt the project. However, these errors should be corrected for the success of the project.

2 Comments

Ques-tion no.	Comments
	Comments should be entered here, e.g. in the event of discrepancies. References to other documents can also be entered.

3 Summary

Review result (team)
The review team should enter its observations and conclusions here.

Review result (software project manager)
The software project manager should enter observations and conclusions here.

Bottom line from the review
For example: The project may proceed as soon as person x has completed task y.

4 Release

First name, last name	Role	Date	Signature
	Software project manager		
	Review team		

H Checklist for post-market surveillance

1 Checklist

This checklist is intended for process assurance and is designed to support developers in the important steps concerning post-market surveillance. To ensure that all required measures in the field of post-market surveillance have been initiated or carried out, this checklist helps review the measures undertaken. The idea is for the review to be conducted by several people and the team and project manager results to be recorded (see section 3).

Working through this checklist helps to ensure that all the relevant steps for compliant surveillance are carried out and that any existing gaps are detected.

Comments on individual questions can be noted in the list and explained at the end of the table.

After the review, the checklist is signed, approved and archived and is thus part of the technical documentation.

	Question	Yes	No	n/a	Weight	Comment
General						
	Has a plan been drawn up for PMS (post-market surveillance) and PMCF (post-market clinical follow-up)?	☐	☐	☐	CD	☐
	Class I: Has a PMS report been drawn up to define the circumstances under which the report will be updated?					
	Class IIa/IIb/III: Has a PSUR (periodic safety update report) been drawn up and can you ensure that it will be updated at least every 2 years (class IIa) or annually (class IIb/III) and that it will be made available to the NB (notified body) for review (class IIb/III)?					
	If necessary, has a PMCF process been defined and can you ensure that the findings from the PMCF will be incorporated in the CER?					
Maintenance						
1	Can you guarantee that modified versions of software due to maintenance work will function on the target platform(s)?	☐	☐	☐	CD	☐
Re-validation						

Question		Yes	No	n/a	Weight	Comment
2	Has the re-validation of software components affected by maintenance work been carried out?	☐	☐	☐	MaD	☐
3	Has the validation plan been updated accordingly?	☐	☐	☐	MaD	☐
Post-market communication						
4	Can you guarantee that customers and affected organisations will be informed about identified security vulnerabilities?	☐	☐	☐	MaD	☐
5	Suggestion: can you guarantee that customers and affected organisations will be informed about regulatory changes that affect use of the SW product?	☐	☐	☐	MaD	☐
6	Can you guarantee that customers and affected organisations will be informed about new features following an update?	☐	☐	☐	MaD	☐
7	Can you guarantee that customers and affected organisations will be informed about fixes following an update?	☐	☐	☐	MaD	☐
8	Can you guarantee that customers and affected organisations will be adequately informed about the impact of changes on safety/security following an update?	☐	☐	☐	MaD	☐
9	Can you guarantee that customers and affected organisations will be adequately informed about the impact of changes on SW identification following an update?	☐	☐	☐	MaD	☐
10	Can you guarantee that following an update customers and affected organisations will have access to information and documents on the update?	☐	☐	☐	MaD	☐
11	Does the risk management process guarantee that complaints and incidents in connection with use of the software relating to security/safety, the obligation to notify the competent authorities, and the need for a security update will be investigated?	☐	☐	☐	CD	☐

Question		Yes	No	n/a	Weight	Comment
12	Can you guarantee that the competent authorities in the relevant states will be informed about security updates (field safety corrective actions)?	☐	☐	☐	CD	☐
Phase-out						
13	Can you guarantee that when software is phased out, health data are protected and that this protection satisfies security requirements?	☐	☐	☐	CD	☐
14	Can you guarantee that post-market data will continue to be collected despite the phase-out and that the clinical evaluation will be updated?				MiD	

Weighting

CD = critical defect -> the project cannot be continued until the defect is rectified

MaD = major defect-> must be addressed, but the next phase can already begin if necessary

MiD = minor defect -> from a regulatory perspective this is no reason to stop the project, but it would make sense to rectify the defect to ensure the project's success

2 Comments

Question no.	Comments
	Comments that arise e.g. in the case of discrepancies should be noted here. You may include references to other documents.

3 Summary

Team review result
The Review Team notes their observations and conclusions here

Software Project Manager review result
The Software Project Manager notes their observations and conclusions here

The bottom line of the review
e.g. the project can be continued as soon as x has completed task y.

4 Approval

First name, surname	Role	Date	Signature
	Software Project Manager		
	Review team		