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GDK Schweizerische Konferenz der kantonalen Gesundheitsdirektorinnen und -direktoren
CDS Conférence suisse des directrices et directeurs cantonaux de la santé
CDS Conferenza svizzera delle direttrici e dei direttori cantonali della sanità

eHealth Suisse

Checklists

Addendum to the guideline for app developers, manufacturers and distributors

Bern, 2 March 2018

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.....	3
B	Checklist for configuration management	9
C	Checklist for the definition phase	14
D	Checklist for the architecture phase.....	18
E	Checklist for the software release phase	21
F	Checklist for data protection and data security	25
G	Checklist for usability.....	29
H	Checklist for post-market surveillance.....	35

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	Im- portan ce	Com- ment		
Risk management aspects from ISO 14971							
1	Has a risk management plan been created and does it comply with the requirements from ISO 14971?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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)?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
3	Has a risk analysis been performed taking into account the following? <ul style="list-style-type: none"> - 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) 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
4	Have the risks been evaluated and has the evaluation result been documented in the risk management file?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
5	Have risk control measures been taken?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>

Question		Yes	No	n/a	Im- portan ce	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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
7	Have the residual risks been evaluated and have the evaluation results been documented in the risk management file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
8	Has a risk/benefit analysis been performed if the residual risk was considered unacceptable and further risk control measures are not feasible?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
9	Have the risks arising due to the risk control measures been analysed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
10	Has the overall residual risk been evaluated based on the criteria stipulated in the risk management plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
11	Has a risk management report been created that documents the results from the review of the risk management process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
Risk management aspects from IEC 62304						
13	Was a risk management process applied in accordance with ISO 14971?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
15	In case older software is used in the medical device: Was this software subjected to a risk management process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
16	Does the software development plan define how to implement software risk management?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

	Question	Yes	No	n/a	Im- portan ce	Com- ment
17	If relevant: Have risk control measures been incorporated into the requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
18	If requirements were defined in the course of software development: Has the risk analysis been re-evaluated and updated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
19	Have the necessary risk control boundaries been defined between software components and has it been ensured that the boundaries are effective?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
20	Has it been investigated in the risk management process whether there are software components that can contribute to hazardous situations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
21	Have causes that contribute to a hazardous situation been identified and documented in the risk management file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
23	If a software component can contribute to a hazardous situation: Have risk control measures been defined and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
24	<p>If risk control measures are implemented as part of a software component's functionality:</p> <ul style="list-style-type: none"> - 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? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
25	Have the implementations of the risk control measures been verified and has the verification result been documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>

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

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

Question 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	Im- portan ce	Com- ment
Configuration elements						
1	Is there an overview of the elements and the corresponding descriptions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
2	Are the software configuration elements clearly identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3	Are the versions of the software configuration elements clearly identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
Project environment						
4	Has the project environment been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
5	Has the directory structure for the workspace been specified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
6	Have the overview and the description of the tools been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
7	Have the overview and the description of the external components been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

Question	Yes	No	n/a	Im- portan ce	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?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
9	Is the management of the configuration elements documented?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
Change management								
10	Is the execution of changes documented?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
11	Is traceability ensured?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
Version management								
12	Is it defined how the builds are versioned?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
Backward compatibility								
13	It is defined how the software should handle backward compatibility?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
Release								
14	Are the conditions defined that must be fulfilled before the issuance of the release can begin?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
15	Is the procedure for issuance of the release defined?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
16	Is the software distribution strategy defined?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
17	Is the update distribution strategy defined?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
18	Is it defined how the software release is to be archived?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
19	Is it defined how long the software release must be archived?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

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

Question 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	Im- portan ce	Com- ment
Planning of software development						
1	Has a software development plan (SDP) been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
2	Are the different software development phases defined in a software development plan (SDP)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3	Are the deliverables for each phase of software development defined in the SDP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
4	Are milestones defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
5	Is traceability of the requirements guaranteed for audits and risk control measures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
6	Are acceptance criteria defined for verification of the deliverables?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
7	Does the documentation in the SDP correspond to the progress of the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
8	Are the system requirements referenced in the SDP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SE	<input type="checkbox"/>

Question	Yes	No	n/a	Im- portan ce	Com- ment		
Software requirements							
9	Are the system requirements (including the risk control requirements) implemented in the software requirements?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
10	Are the software requirements not mutually contradictory?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
11	Are the software requirements formulated to avoid ambiguity?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
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?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
13	Can the software requirements be clearly identified?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
14	Can the software requirements be traced back to system requirements or other sources?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
15	Was the risk analysis for the medical device re-evaluated after definition of the software requirements and modified if necessary?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
16	Were the system requirements re-evaluated after definition of the software requirements and modified if necessary?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SE	<input type="checkbox"/>

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

Question 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	Im- portan ce	Com- ment
General information						
1	Has the software architecture been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
2	Are the system and software requirements implemented along with the architecture?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3	Are the requirements for risk control implemented by the architecture?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
4	Are the interfaces supported between the individual software components and between the software components and hardware?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
5	Does the architecture support proper operation of all SOUP components?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

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

Question 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	Im- portan ce	Com- ment
General information						
1	Is the software up-to-date (latest version)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
2	Have all errors in the error list been corrected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3	Are the software anomalies documented and do not lead to critical errors?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
4	Has debugging and test code been removed from the software?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
5	Backup completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
6	Have configuration statuses been created that include all components?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
7	Has the installation guide been created?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
8	Has the risk analysis been performed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
9	Has quality control been performed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
10	Have the copyright, license, QM and legal documents been reviewed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
11	Is the software release documentation ready?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>

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

Question 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	Im- portan ce	Com- ment
Data protection and data security (under Swiss law)						
1.	Have the app users consented to the processing of their personal data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3.	Are app users informed about the purposes for which the app processes their personal data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
4.	Does the app process only as much data as it needs to fulfil the specified purpose or purposes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

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

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

Question 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	Im- portan ce	Com- ment
General information						
1	Has the intended purpose of the software product been determined and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
2	Have the user profile and operating environment been determined and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
3	Have the following points been determined and documented in the specification for the application? <ul style="list-style-type: none"> – Intended medical indication – Intended patient group – Body part or tissue type – Intended user profile – Intended usage conditions – Modes of operation 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
4	Have risk control measures been defined and documented for unacceptable risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
5	Have the safety-relevant functions been defined and itemised?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
6	Have the main operating functions been defined and itemised?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>

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

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

Question		Yes	No	n/a	Im- portan ce	Com- ment
30	Does the accompanying documentation contain a summary of the application specification for the software product?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
31	Does the accompanying documentation contain a concise description for the following points (if relevant for usage)? <ul style="list-style-type: none"> - Functional principle - Significant physical characteristics - Significant performance features - Intended user profile 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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? <ul style="list-style-type: none"> - Training materials are provided - Access to training materials is ensured - Training is provided 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>

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

Question 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 should support developers with the main steps related to post-market surveillance. To ensure that all required measures in the area of post-market surveillance are moving forward or are completed, this checklist can be used to review the performed measures. 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.

Question		Yes	No	n/a	Im- portan ce	Com- ment
Maintenance						
1	Is it guaranteed that versions of the software that are modified due to maintenance will function on the target platform(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
Re-validation						
2	Have the software components that were affected by the maintenance been re-validated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
3	Has the validation plan been updated accordingly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
Post-market communication						
4	Is it guaranteed that customers and affected organisations are informed about recognised security vulnerabilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
5	Recommendation: Is it guaranteed that customers and affected organisations are informed about regulatory changes that impact the usage of the software product?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
6	Is it guaranteed that customers and affected organisations are informed about new features after an update?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>

Question		Yes	No	n/a	Im- portan ce	Com- ment
7	Is it guaranteed that customers and affected organisations are informed about the errors that were corrected after an update?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
8	Is it guaranteed that customers and affected organisations are adequately informed about an update's security impact after the update?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
9	Is it guaranteed that customers and affected organisations are informed about an update's impact on software identification after the update?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
10	Is it guaranteed that customers and affected organisations have access to information and documentation about an update after it has occurred?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ME	<input type="checkbox"/>
11	Is it guaranteed (in the risk management process) that complaints and incidents related to usage of the software are investigated in terms of their safety (or security) relevance, any reporting obligation required by the responsible authorities, and the need for a safety (or security) update?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
12	Is it guaranteed that the responsible authorities in applicable countries are informed about safety (or security) updates (field safety/security measures)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
Phase-out						
13	Can it be guaranteed that health data is protected when the software is decommissioned and that this protection meets the security requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CE	<input type="checkbox"/>
14	Is it guaranteed that post-market data will still be collected despite the decommissioning and that the clinical evaluation will be updated?				SE	

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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		