Checklist for changes under MDR article 120.3

Background

Article 120(3) of (EU) 2017/745 (MDR) allows that devices in accordance with 93/42/EEC (MDD) can continue to be placed on the market if:

- The relevant MDD certificates are valid
- The devices continue to be compliant with MDD
- The following requirements of the MDR are met:
    - post-market surveillance (including PPRC),
    - vigilance,
    - registration of site and products, and
    - no significant changes to the design and the intended purpose.

This checklist is used to determine if the change in the intended purpose or design of the device is a significant as per article 120(3).

Requirements and responsibilities

This guidance is used for MDR article 120(3) and is to be completed in addition to the requirements in NBOG BPG 2014-3 “Guidance for manufacturers and Notified Bodies on reporting design changes and changes of quality system”.

When using this checklist, the following mandatory instructions apply:

- Any change made to the approved design or intended purpose of an existing MDD product under article 120(3) of MDR must be assessed within this checklist.
- This checklist is to be approved by the person responsible for regulatory compliance (PRRC).
- The checklist consists of 6 flowcharts (taken from MDCG 2020-3):
    - Main Chart
    - Flow Chart A: Intended purpose
    - Flow Chart B: Design and performance specification
    - Flow Chart C: Software
    - Flow Chart D: Material
    - Flow Chart E: Sterilization method or packaging design
- All charts must be completed for each change. If a chart is not applicable, it is to be justified in the footer of the chart.
- If a change includes multiple changes, each change must be assessed on its own. In addition, the cumulative impact of changes must be assessed.
- Examples of significant and non-significant changes and further guidance are given in MDCG Guidance 2020-3.

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- If the assessment concludes that the change is significant, the change process shall be discontinued. Decision must be made by top management if and how to follow-up the change.
- The notified body will have to be notified of any change for class III or active implantable devices.
    - Using this checklist, we will determine if the change is significant or not.
    - Non-significant changes will be notified to our notified body. The notified body will review and agree or disagree to our notification.
    - The change can only be implemented once the notified body agreed that the change is non-significant.
    - The non-significant change will be listed continuously in the list of changes.
- All non-significant changes for class I and class II devices will be listed continuously in the list of changes
    - The list of non-significant changes to class I and class II products will be submitted, if requested, to the notified body ahead of the annual surveillance audits.

References

[1] (EU) 2017/745 MDR
[2] NBOG BPG 2014-3 “Guidance for manufacturers and Notified Bodies on reporting design changes and changes of quality system”
[3] MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

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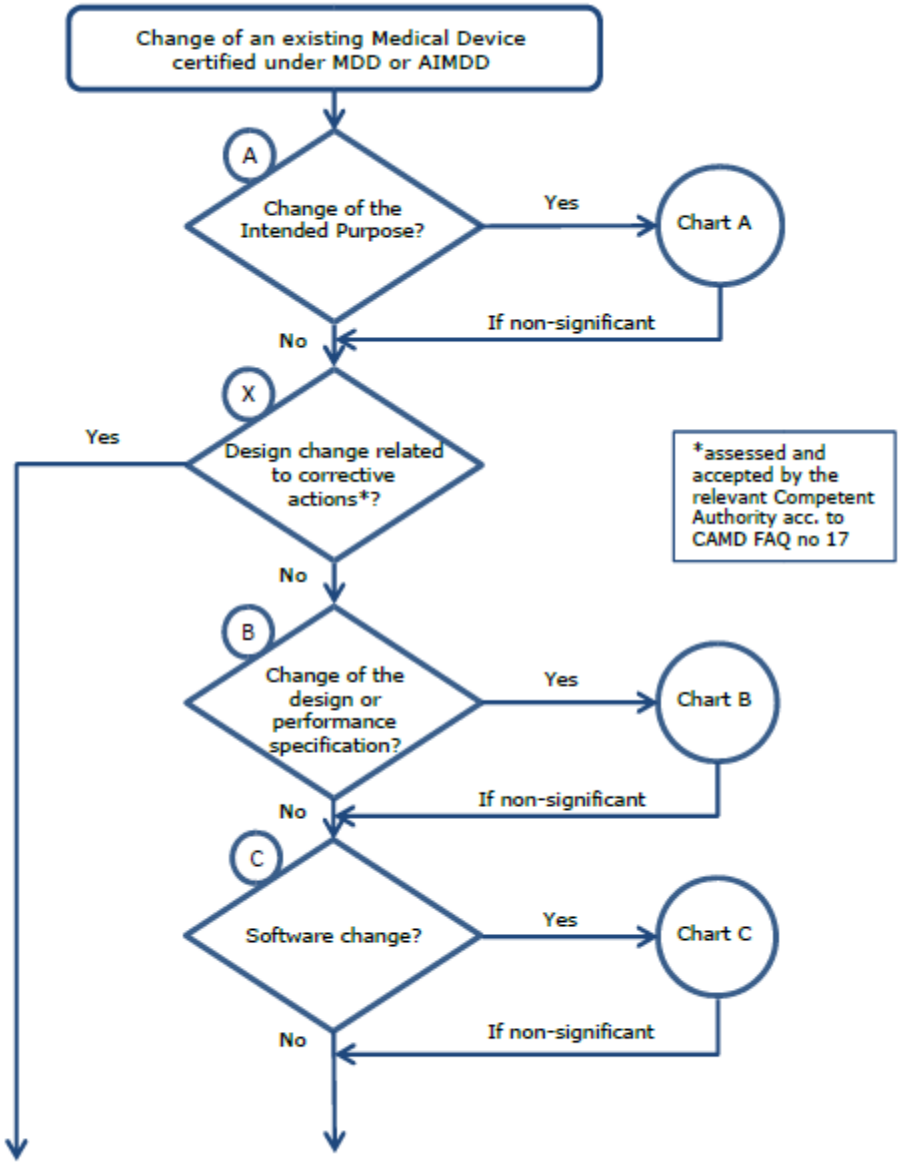
Main chart (Part 1)



Main chart (Part 2)

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com

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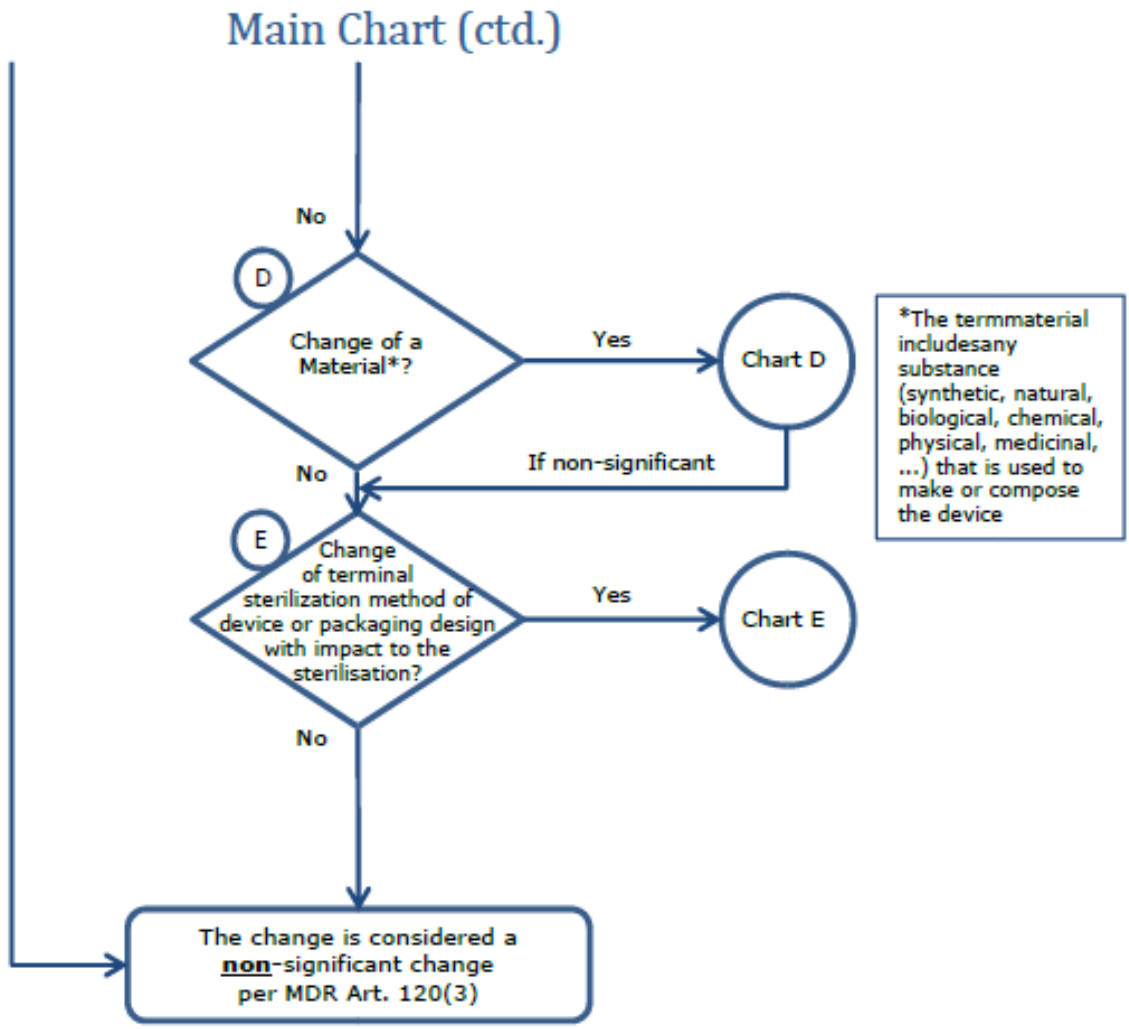
Main chart (Part 2)



Conclusion:

The change is significant ☐ yes ☐ no

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com

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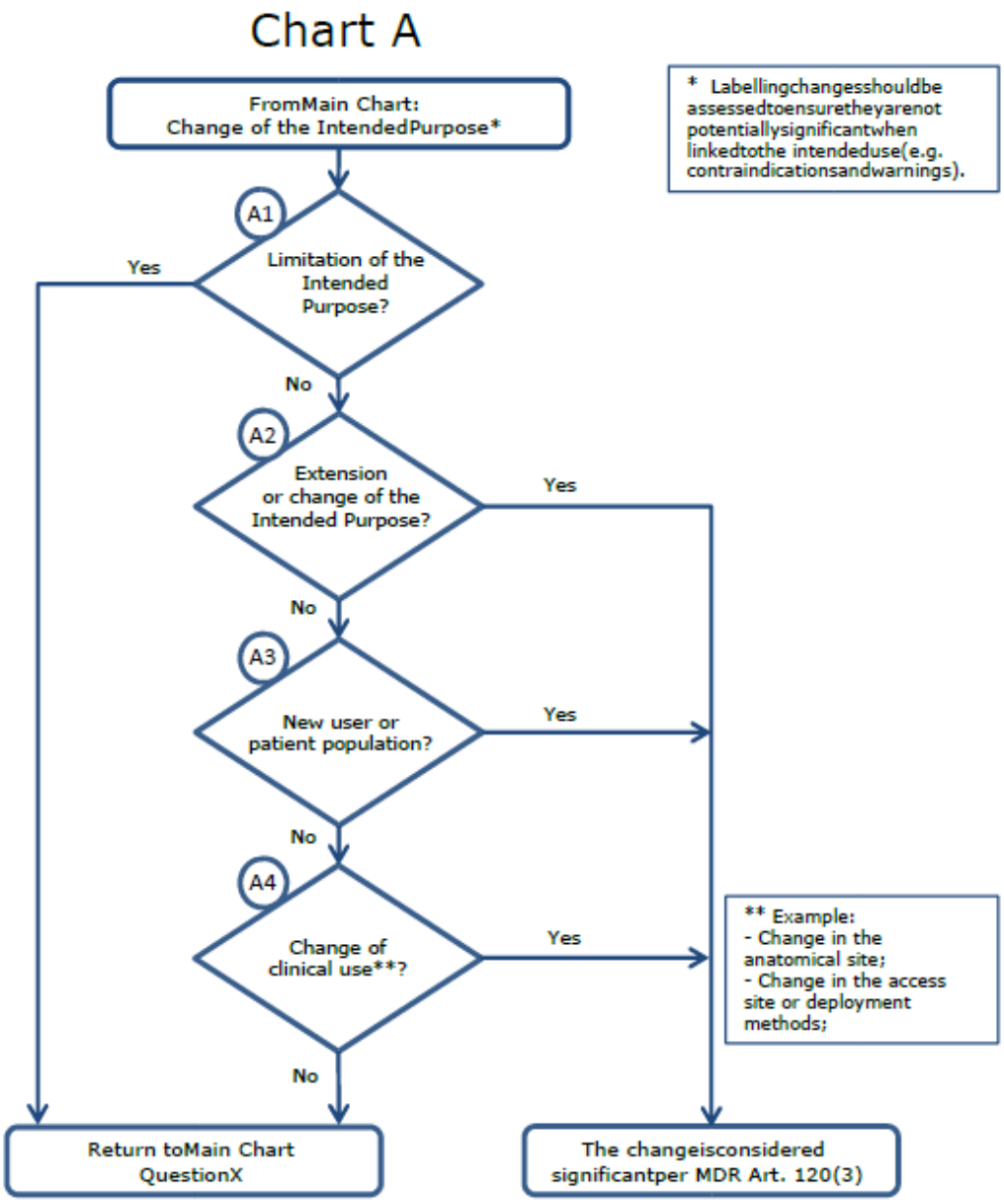
Flow Chart A: Intended purpose



Conclusion:

☐ The flowchart is not applicable because:

The change is significant ☐ yes ☐ no

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com

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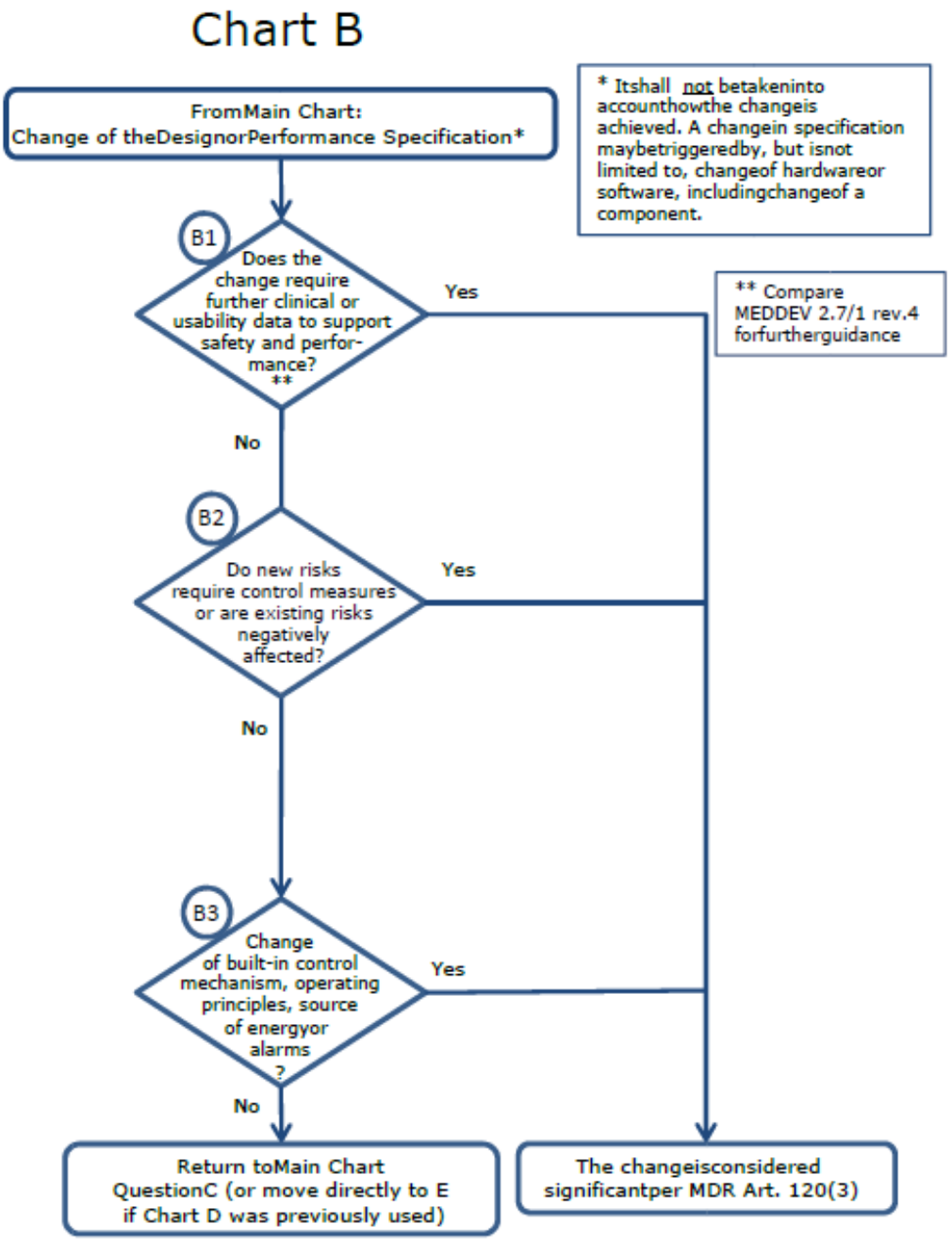
Flow Chart B: Design and performance specification



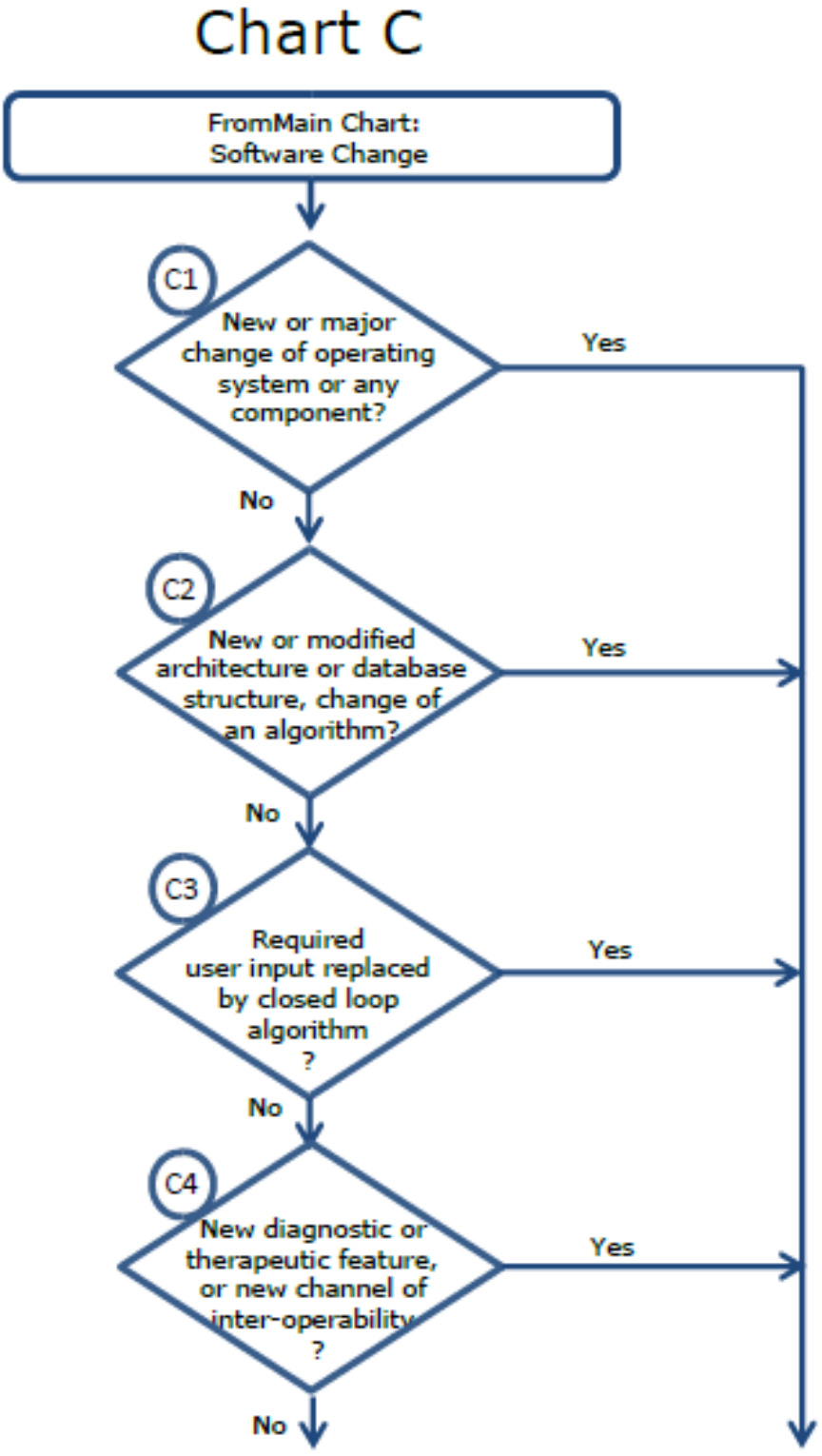
Conclusion:

☐ The flowchart is not applicable because:

The change is significant ☐ yes ☐ no

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com

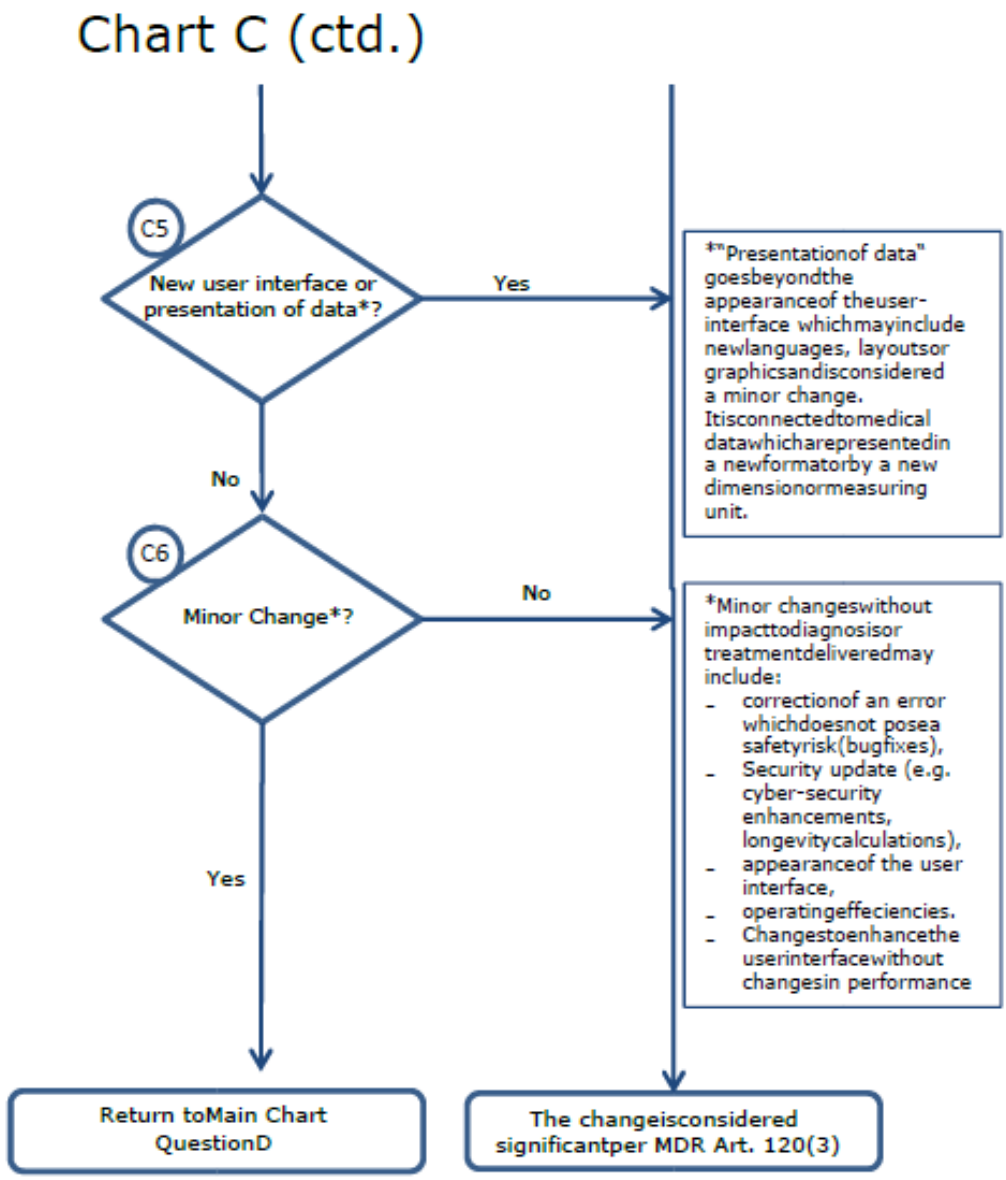
Flow Chart C: Software (Part 1)



Software (Part 2)

Checklist for changes under MDR article 120.3

Flow Chart C: Software (Part 2)



Conclusion:

☐ The flowchart is not applicable because:

The change is significant ☐ yes ☐ no

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Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
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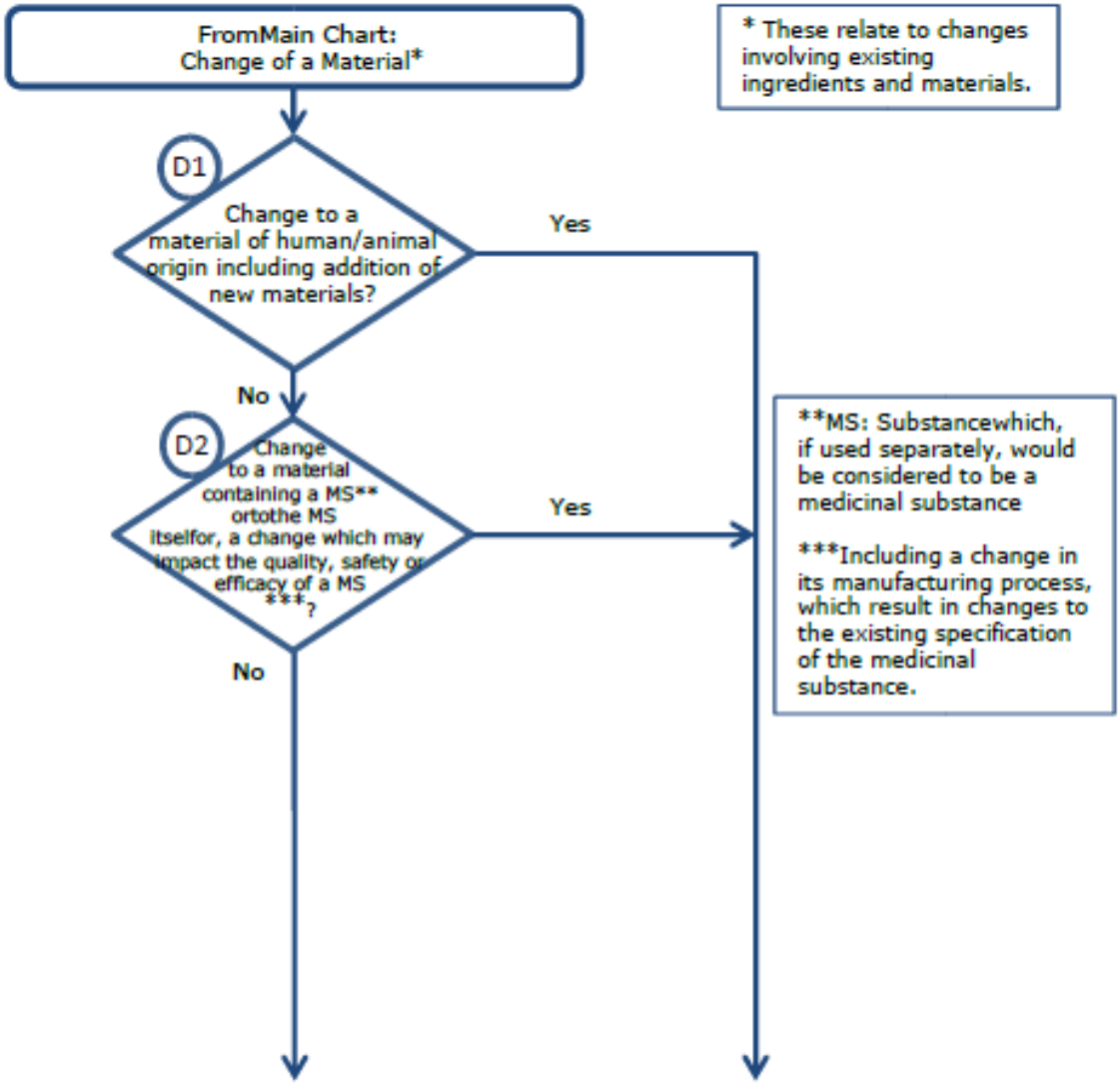
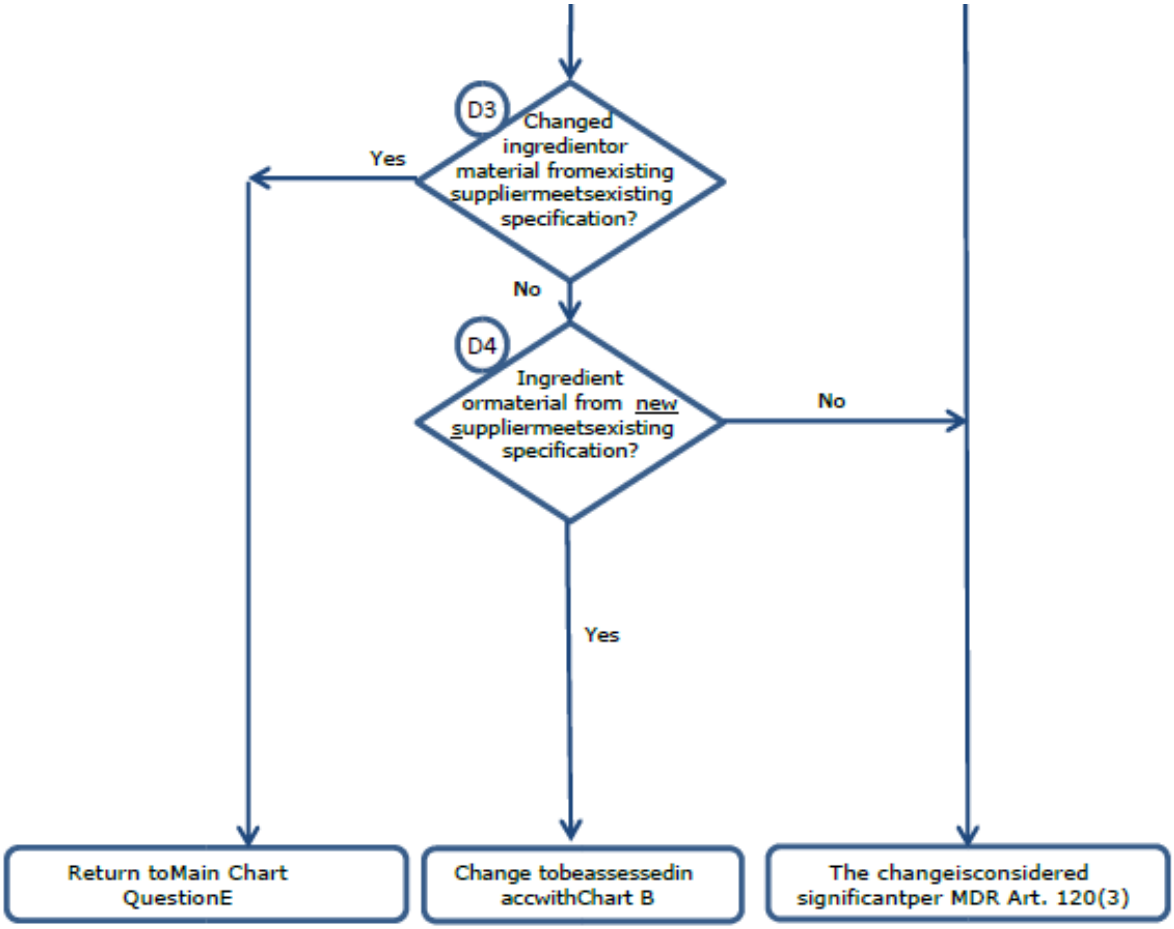
Flow Chart D: Material (Part 1)



Material (Part 2)

Checklist for changes under MDR article 120.3

Flow Chart D: Material (Part 2)



Conclusion:

☐ The flowchart is not applicable because:

The change is significant ☐ yes ☐ no

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Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com

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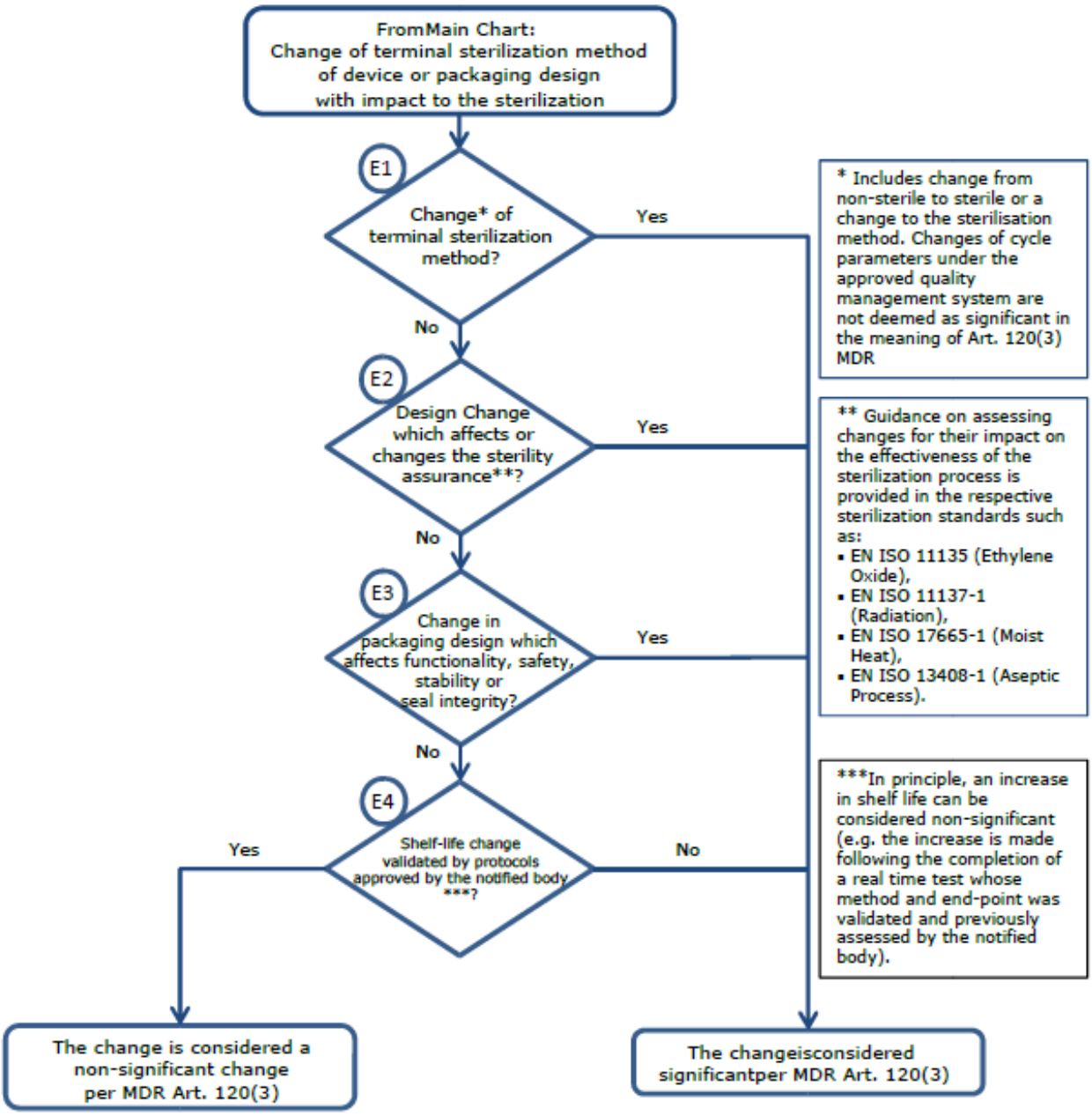
Flow Chart E: Sterilization method or packaging design



Conclusion:

☐ The flowchart is not applicable because:

The change is significant ☐ yes ☐ no

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
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Conclusion:

The change is considered significant

☐ yes ☐ no

In case of multiple changes within one assessment:
The cumulative impact of change is considered significant

☐ yes ☐ no, because (justify):

☐ The product is a class III product and/or active implantable device. Notification to notified body will have to be notified prior to implementation.

Change Notification number: _____

☐ The product is a class I or class II device and notification to notified body is not needed prior to implementation.

Approval by PRRC

_____
Date / Name / Signature

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