Joint Industry Position
on
Significant Changes According to MDR Article 120(3)

February 2019

Background

Article 120(3) of the Medical Device Regulation (EU) 2017/745 (MDR), states that devices which have a valid certificate issued by a Notified Body under the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) or the Medical Devices Directive 93/42/EEC (MDD), may be placed on the market after the date of application of the MDR under certain conditions, but no later than 26 May 2024.

Questions 8 and 9 of the CAMD Transition Sub Group guidance: "*FAQ – MDR Transitional provisions, V1.0 of 17. January 2018*" (hyperlink) state that the certificates covered by MDR Article 120(3) include *„all certificates which are commonly issued by Notified Bodies with reference to the Council Directives MDD and AIMDD".* Consequently, such certificates may exist for medical devices of all risk classes, including class I sterile devices and class I devices with measuring function, other than devices of the lowest class I.

A significant change in design or intended purpose of a device after the date of application of the MDR may prevent the manufacturer from continuing to place that device on the market until compliance with the MDR has been established. Therefore, it is important for the manufacturers to get clarity on the significant changes to be considered under MDR Article 120(3).

It is also important that the AIMDD and MDD certificates remain valid following changes that are not significant or unrelated to design or intended purpose, apart from the discussion about significant changes per MDR Article 120(3).

Scope and legal reference

The flowcharts in the Appendix below have been developed exclusively to help identify those changes to a device considered a "significant change in design or a significant change in the intended purpose" under MDR Article 120(3). Any assessment should be made on a case-by-case basis.

These flowcharts do not provide an opinion on whether a change:

- needs submission to a notified body*;*
- requires assessment by a notified body*;*
- yields a certain assessment result; or
- results in an amendment of the related and valid certificate

under the surveillance provided by the notified body who issued the related certificate required under MDR Article 120(3) and to confirm ongoing compliance with the AIMDD or MDD.

The flowcharts are based on NBOG's Best Practice Guide 2014-3*: „Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System"* (hyperlink). Chart C, specific to software, incorporates elements from Annex VI, Part C, Section 6.5. of the MDR (hyperlink) to identify modifications that may be considered as significant change in (software) design.

Changes of organisations (manufacturer, authorised representative, distributors and suppliers, including their respective name, address and legal status), changes of the quality management system and quality control activities, changes to the manufacturing facility or to the manufacturing technology and other changes which are unrelated to or do not coincidentally, collaterally or consequently affect the design or intended purpose of the device must not fall within the scope of these flowcharts when deciding about the significance of the change. Consequently, these changes will be verified by the Notified Body as part of the surveillance activity and must not impact the validity of certificates.

The flowcharts also take into account *CAMD Transition Sub Group: "FAQ – MDR Transitional provisions, V1.0 of 17. January 2018"*, especially questions 3 and 17.

Note: This paper does not cover significant change under the In Vitro Diagnostic medical devices Regulation (EU) 2017/746.

Outcomes

The assessment of a proposed change by using the main flowchart and any of the applicable sub-charts in the Appendix, allows the user to decide whether or not the change is considered significant in the design or intended purpose of the device under MDR Article 120(3).

If the assessment concludes that the change is a „significant change in design or intended purpose“ under MDR Article 120(3), the implementation of the change prevents the manufacturer from continuing to place that device on the market.

If the assessment concludes that the change is „not a significant change in design or intended purpose“ under MDR Article 120(3), the implementation of the change after the date of application shall not invalidate any related MDD or AIMDD certification and the manufacturer may continue to place the device on the market until 26 May 2024 as long as the certificate is not expired.

If any other change is not the result of a change to design and/or intended purpose (e.g. quality management system and other administrative changes) or the change does not result in a coincidental, collateral or consequential change of design or intended purpose, the implementation of the change after the date of application shall not invalidate any related MDD or AIMDD certification and the manufacturer may continue to place the device on the market until 26 May 2024 as long as the certificate is not expired.

However, these non-significant changes may require an amendment of the existing valid AIMDD or MDD certificate, to reflect properly the actual status of the device or manufacturer after the change. The notified body that has issued the initial certificate must be able to issue an amendment (notwithstanding MDR Article 122) by using the exclusion of prejudice regarding MDR Article 120(3) and (4) therein and in accordance with notified body’s responsibility under the second section of MDR Article 120(3).

Alternatively, and depending on the device’s final conformity assessment to with the requirements of the AIMDD or MDD, the notified body that issued the AIMDD or MDD certificate may confirm in writing (after having reviewed manufacturer’s description of the proposed change) that the implementation of the change does not represent a change in design or intended purpose under MDR Article 120(3) and that the related AIMDD or MDD certificate remains valid after the date of application of the MDR, but no longer than its expiry date or 26 May 2024, whichever comes first.

Appendix

Design Changes and Changes of the Intended Purpose
Which may be Considered „Significant“ When Interpreting
the First Sentence of MDR Article 120(3)

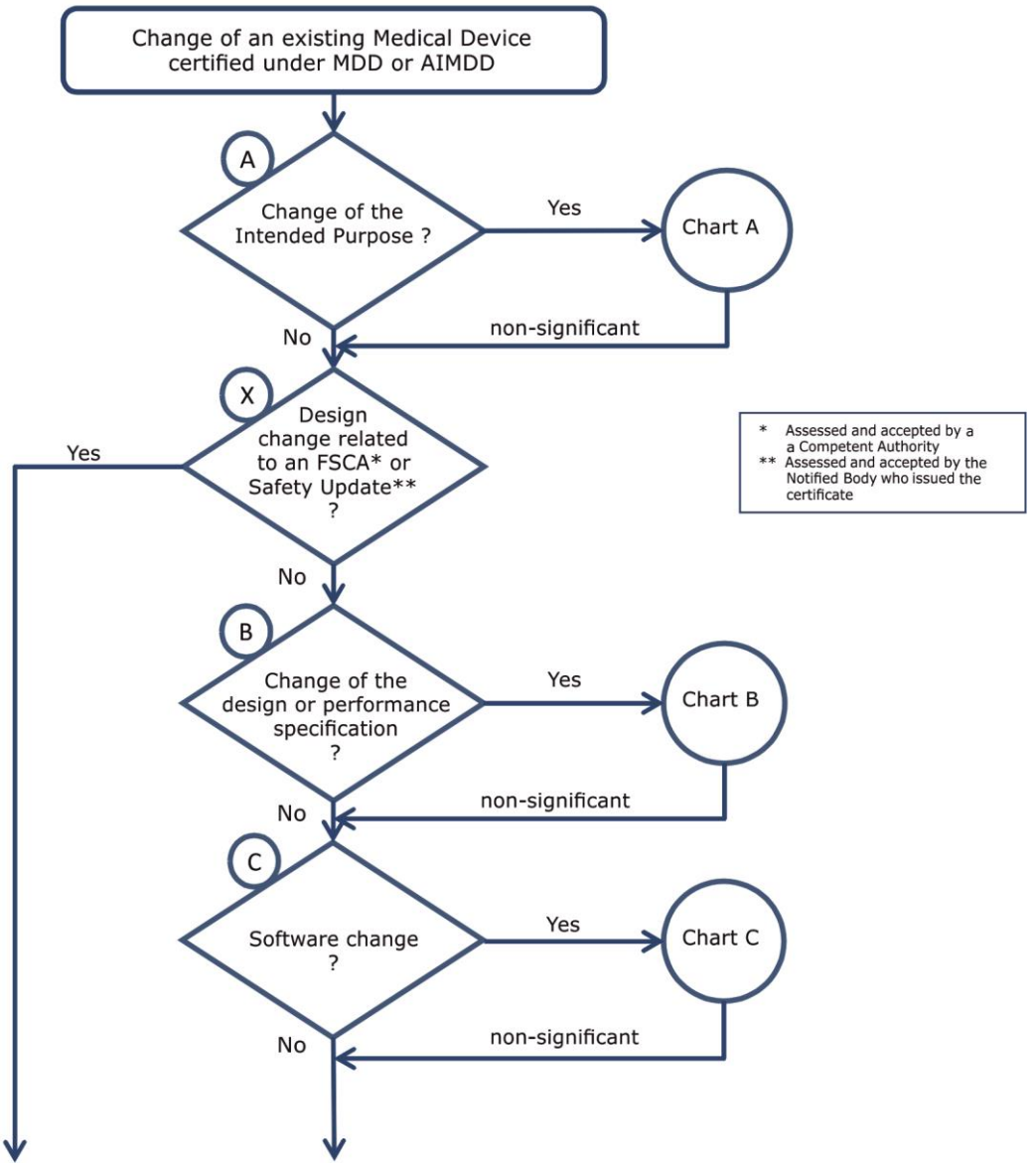
How to use the flowcharts

The flowcharts are divided into a main chart and five sub-charts (A to E). The user follows the main chart from the beginning, with the aim of arriving at end of the main chart with the determination “The change is considered a non-significant change of design or intended purpose per MDR Article 120(3)“. There are six categorical questions in the main chart which may send the user into one or more sub-charts with more detailed questions (or in case of Question X directly to the determination: “The change is considered a non-significant change of design or intended purpose per MDR Article 120(3)“).

- If the answer to every question in a sub-chart leads to „non-significant change“, then the user returns to the main chart.
- If the result for all sub-charts that apply is „non-significant change“, the final determination is: “The change is considered a non-significant change of design or intended purpose“.
- However, if any sub-chart delivers the result „significant change“, the change being assessed is a „significant change in design or intended purpose“ of a device according to the MDR Article 120(3).

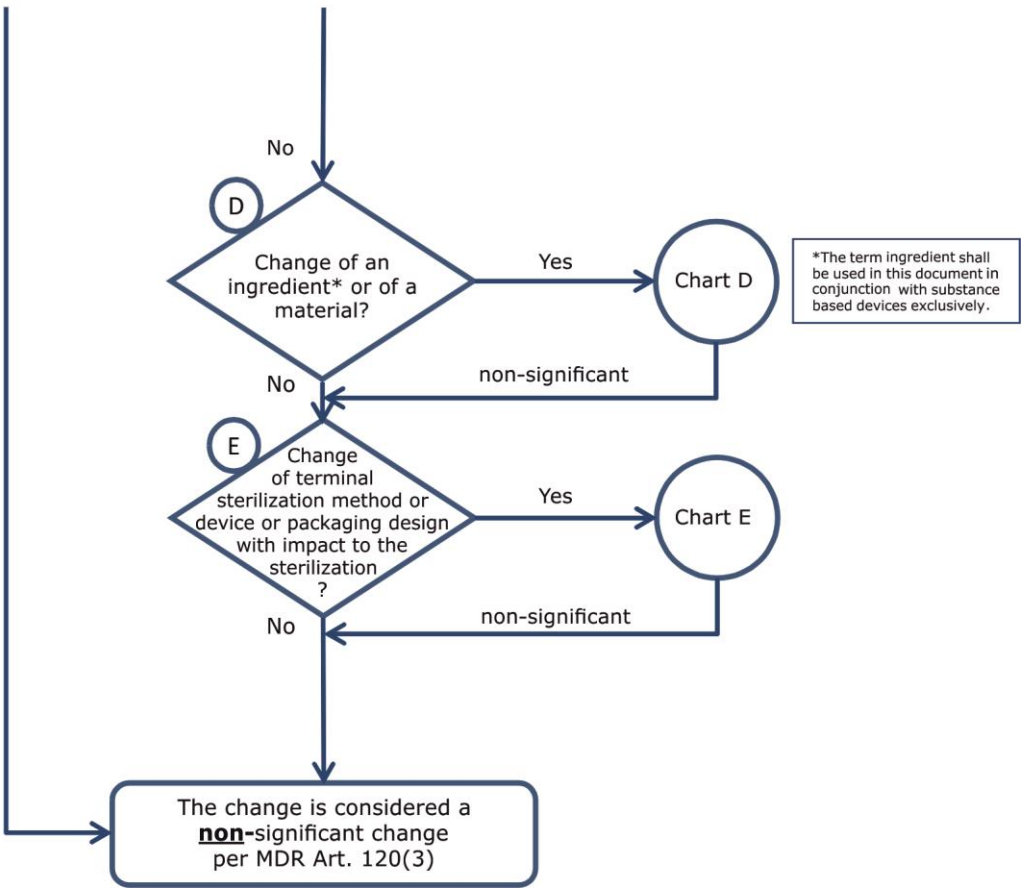
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Main Chart



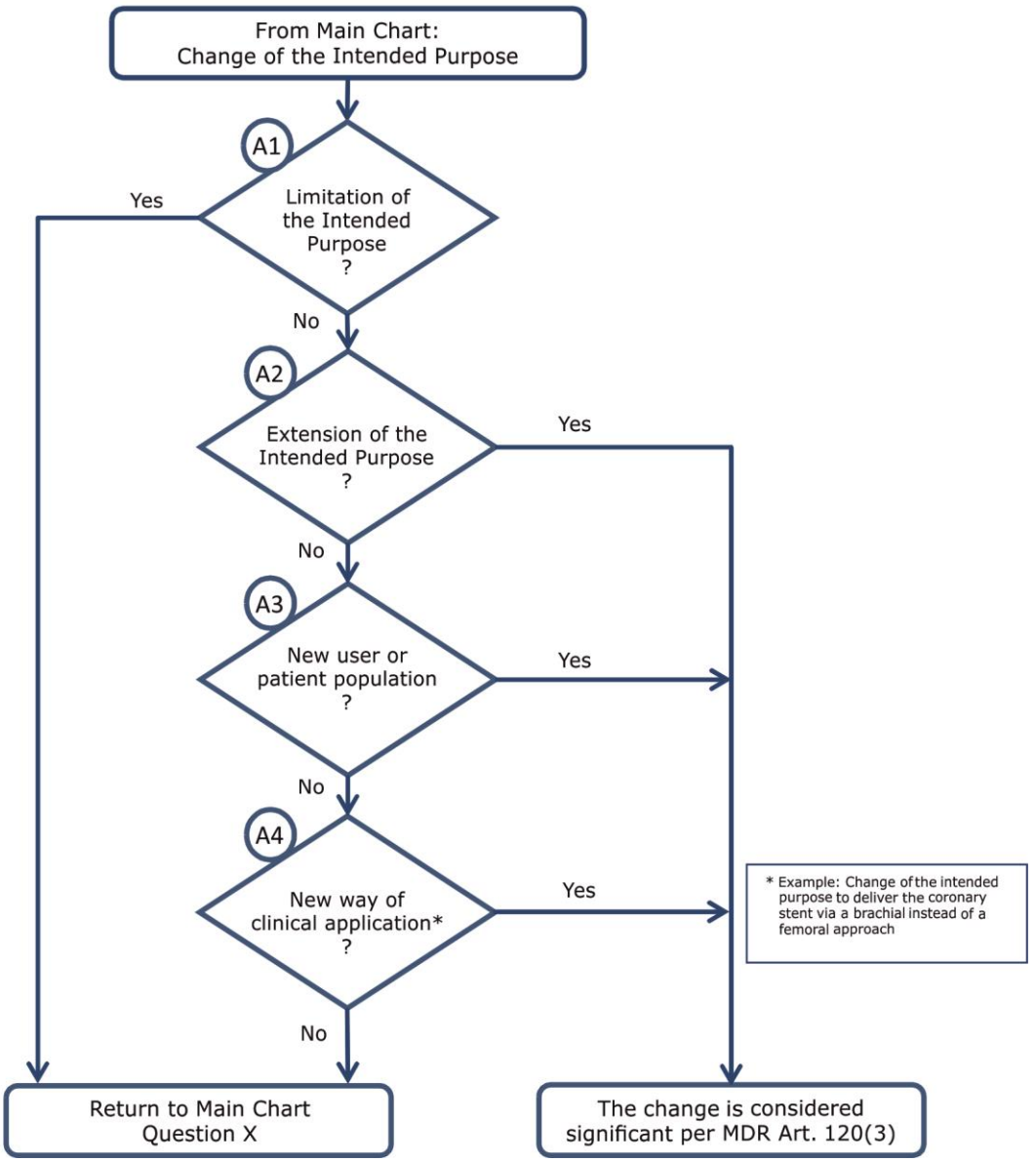
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Main Chart (ctd.)



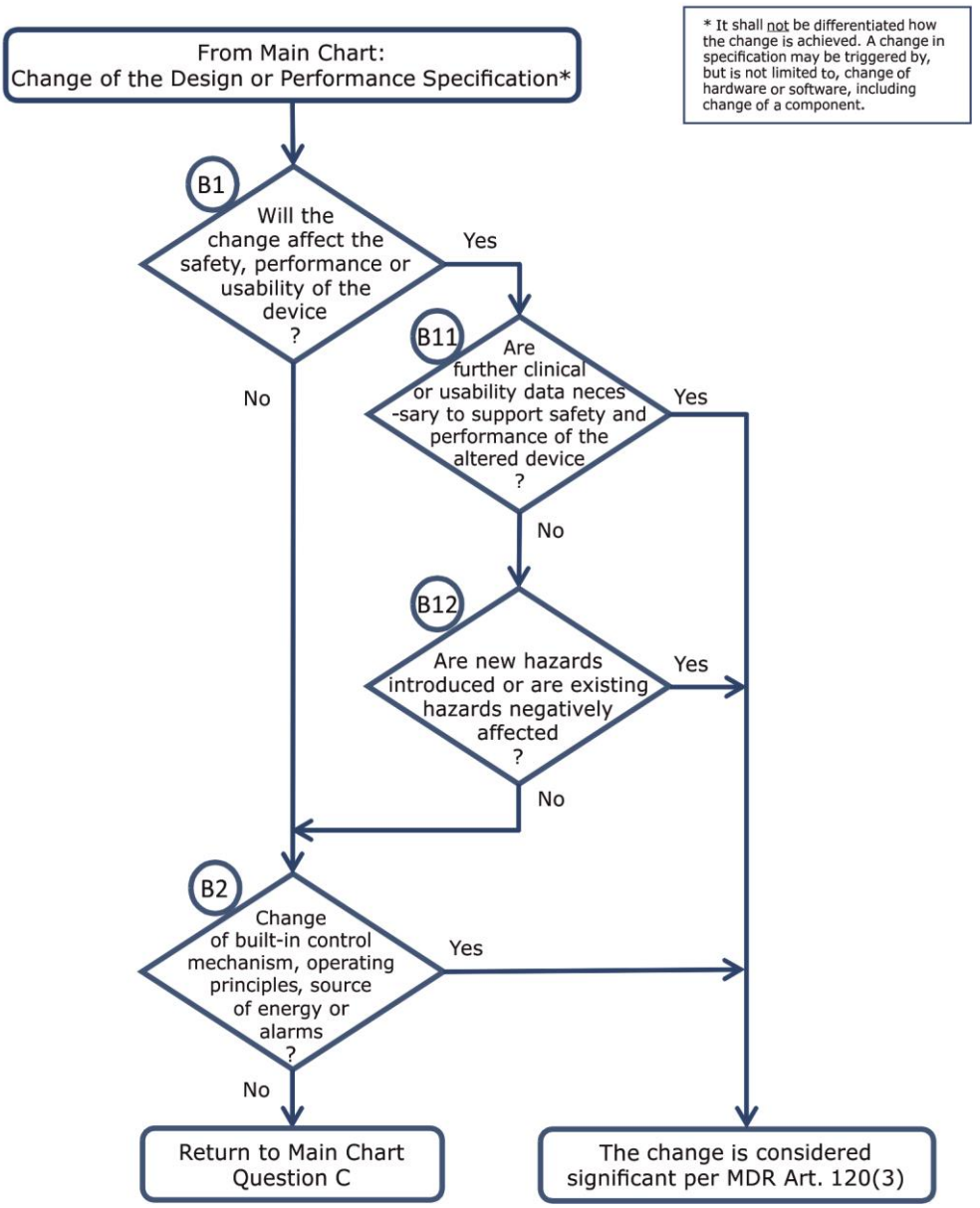
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart A



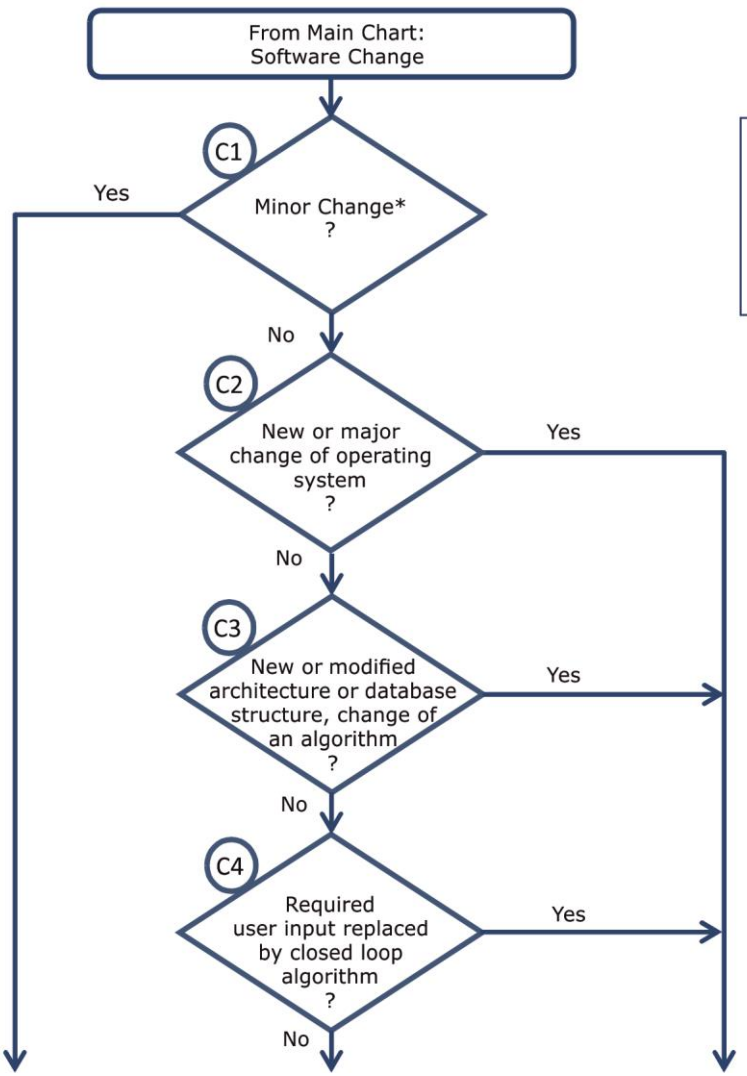
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart B



Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

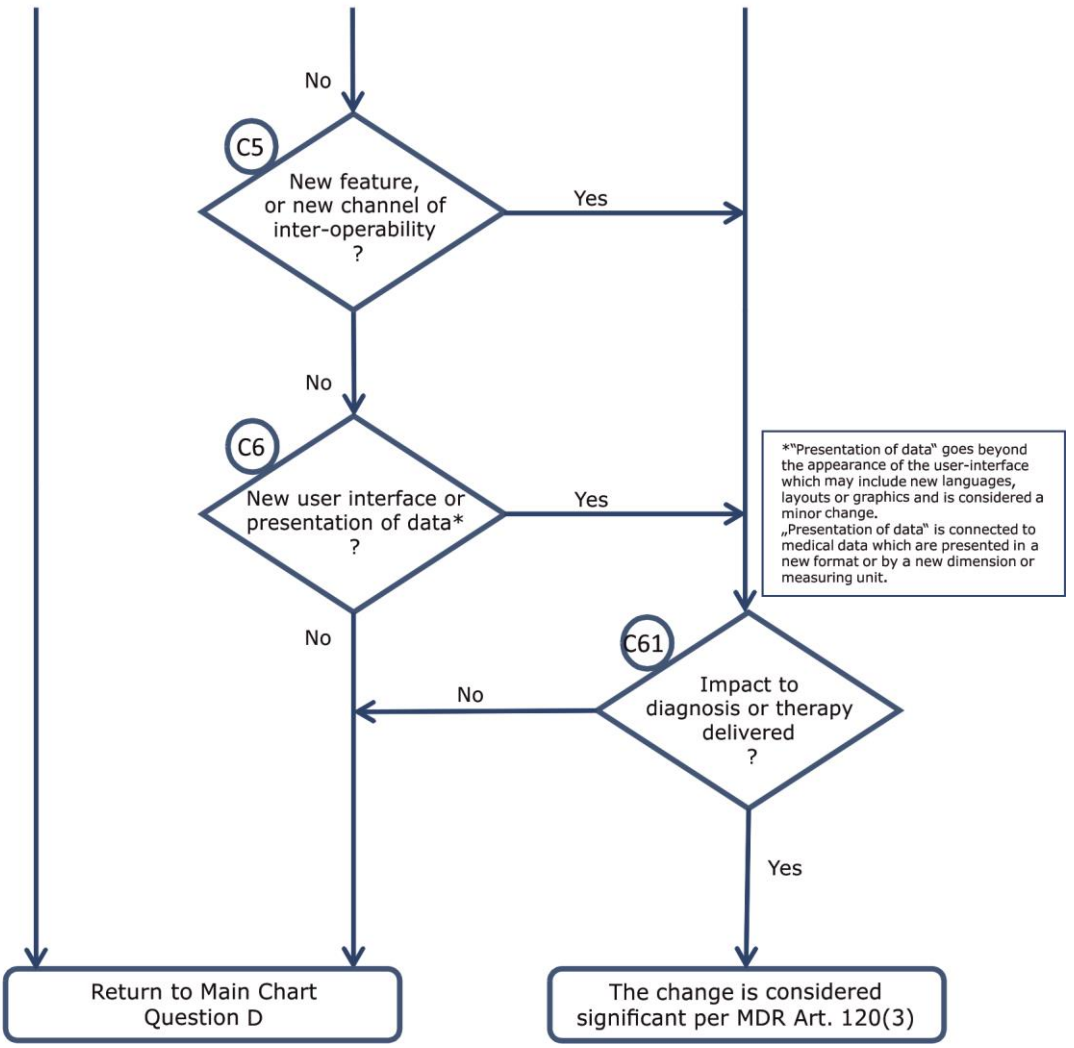
Chart C



*Minor changes without impact to diagnosis or treatment delivered may include:
- correction of an error which does not pose a safety risk (bug fixes),
- Security update (e.g. cyber-security enhancements, longevity calculations),
- new non-medical features,
- appearance of the user interface,
- operating effeciencies.

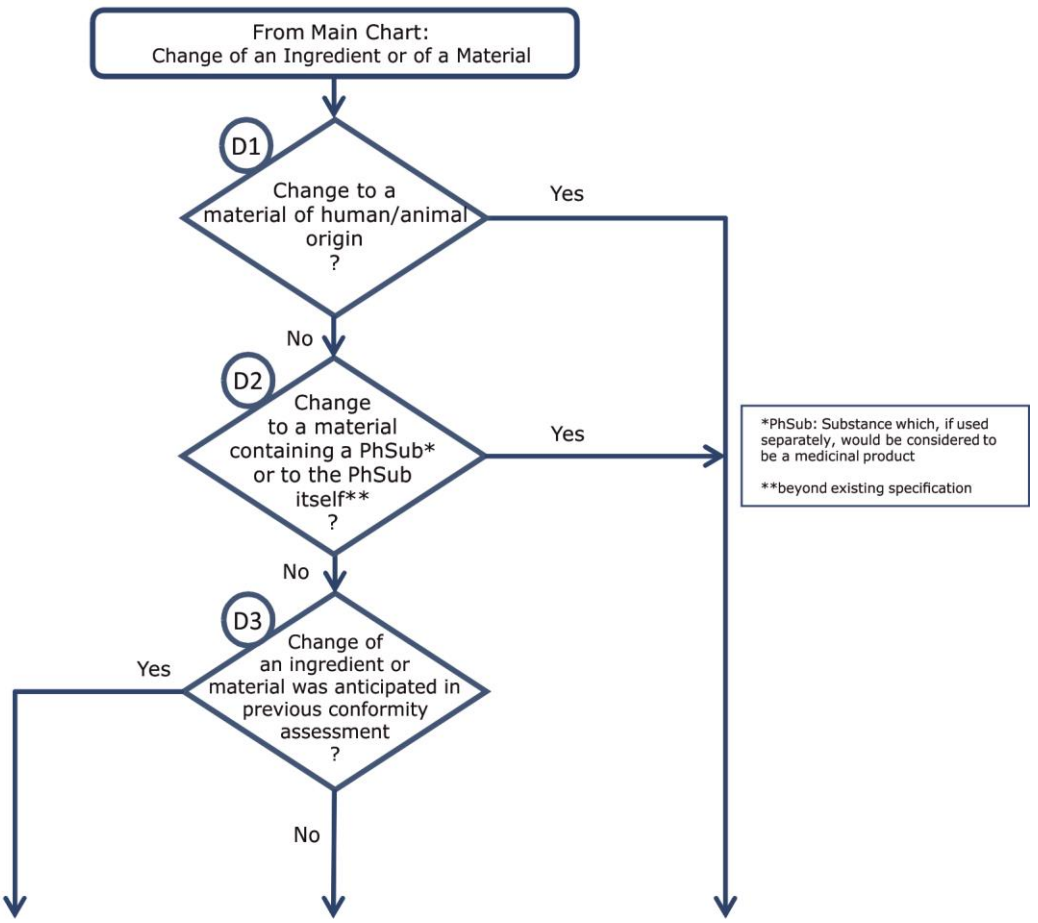
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart C (ctd.)



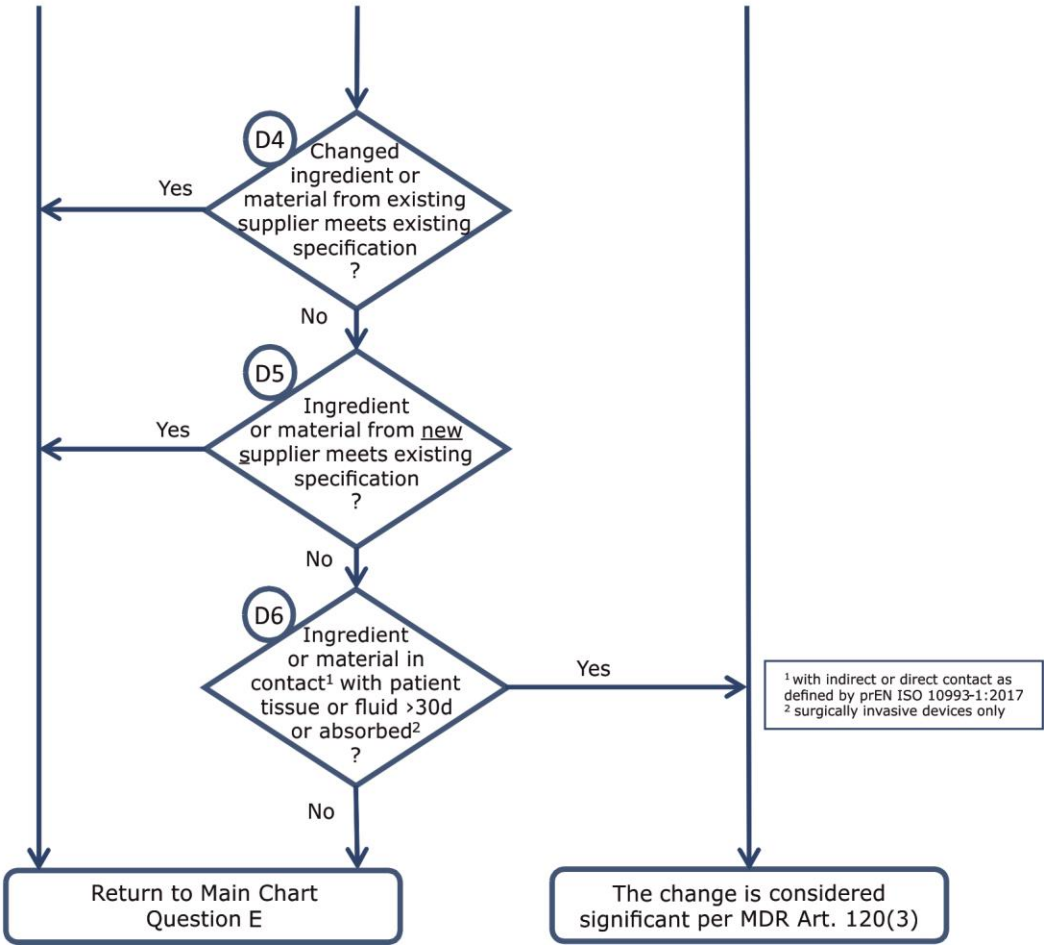
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart D



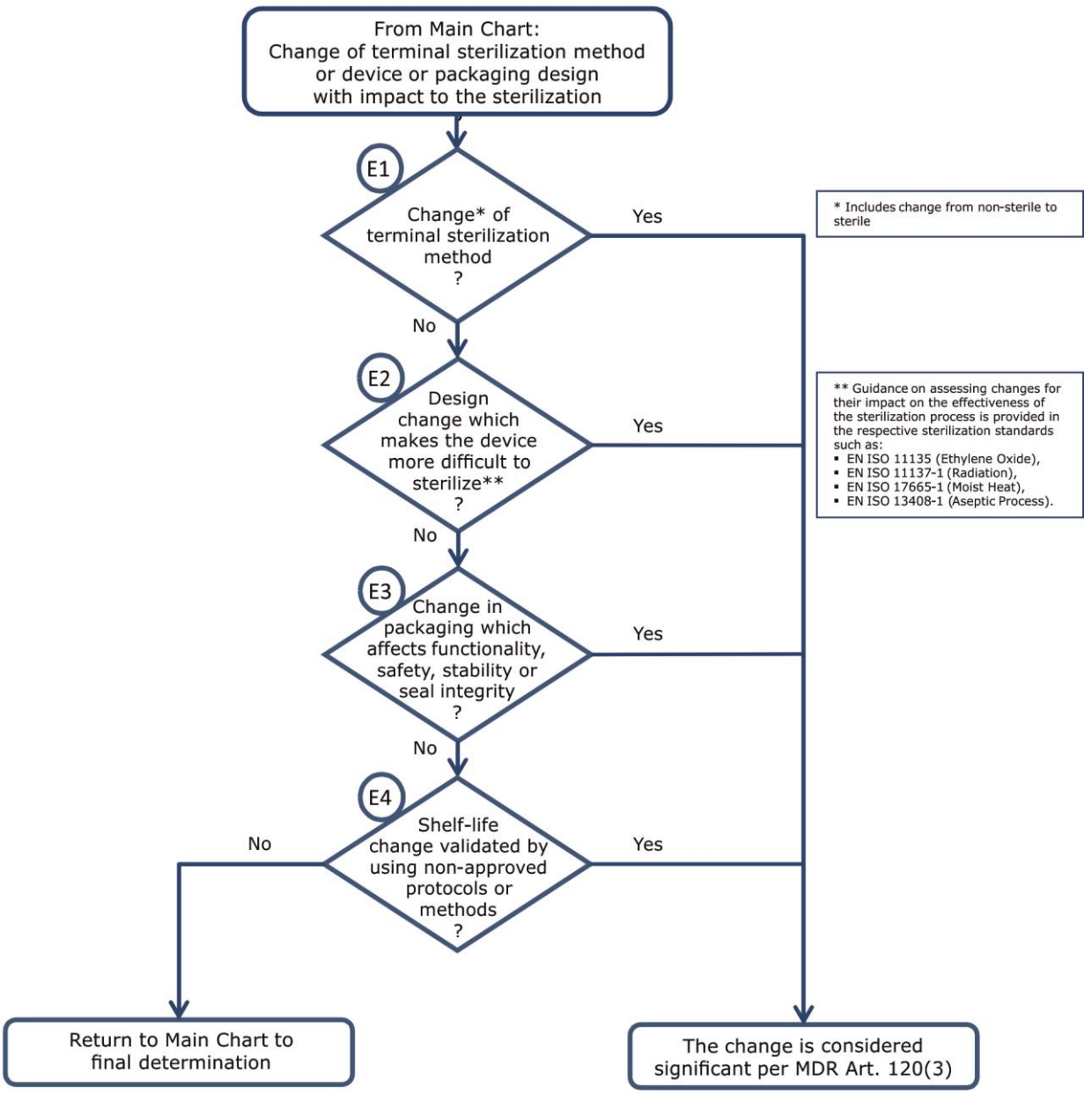
Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart D (ctd.)



Design Changes and Changes of the Intended Purpose Which may be Considered „Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Chart E



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