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

March 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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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[1]

1 Introduction

Article 120(2) and 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 or put into service after the date of application of the MDR under certain conditions and 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"[2] 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".

Conditions referred to in the first paragraph require that no significant changes in design or intended purpose of a device be performed after the date of application of the MDR. Therefore, it is important for manufacturers and notified bodies 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 with regard to design or intended purpose, provided that the required surveillance is carried out by the notified body that issued the certificate. See also Question 17 of the above mentioned CAMD guidance[2].

2 Scope

This guidance document is intended to provide clarification on the changes to a device that should be considered a "significant change in design or a significant change in the intended purpose" under MDR Article 120(3). Assessments should be made on a case-by-case basis.

[1] The principles outlined in this guidance can be applied also for class I devices requiring the involvement of a notified body for the first time.

[2] https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf

This guidance document does not elaborate on the process for manufacturers' submission and notified bodies' assessment of such changes as these should be part of the conformity assessment process and surveillance defined by the relevant notified body under the MDD or AIMDD. It is expected that manufacturers adjust their change notification procedures, i.e. their provisions to inform their notified body on changes, in accordance with the principles outlined in this guidance until the date of application of the MDR. The adjusted procedures will be subject to notified body assessment within their surveillance activities according to MDR Art. 120(3).

3 Changes to Directive certificates

It is important to highlight that no issuing of new MDD/AIMDD certificates, including modified, amended or supplemented certificates, is allowed under MDR Article 120(3). In particular, if the manufacturer wishes to make a "significant change in design or intended purpose" under MDR Article 120(3), the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the Directives.

4 Assessment of changes' significance in accordance with MDR Article 120(3)

In line with agreed arrangements for notification of changes between the manufacturer and the notified body according to the AIMDD/MDD (e.g. contractual relationships, approved procedures) changes and their implementation will be verified by the notified body as part of the surveillance activities, or following a manufacturer's submission for prior approval. The outcome of this verification will determine whether a certificate in accordance with AIMDD/MDD remains valid according to Article 120 MDR. To use this derogation from Article 5 MDR manufacturers are not allowed to make significant changes in design or a significant changes in the intended purpose. In case of doubt whether a change is significant they should ask their notified body.

For instance, administrative changes of organisations are considered in principle as non-significant. This includes changes of the manufacturer's name, address or legal form (legal entity remains) or changes of the authorised representative.

Furthermore, all changes not having an impact on the design or the intended purpose of the device can be regarded as not significant in the meaning of MDR Article 120(3). This is the case for example of relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers, or of certain changes of the quality management system, provided that the conditions for which the conformity assessment certification was granted are maintained. Nevertheless, such changes continue to be subject to the agreed notification procedure identified in the first paragraph of the current section. The manufacturer should always remain responsible for providing evidence that all the above-mentioned changes do indeed neither affect the design nor the intended purpose.

On the other hand, when the change is likely to affect the design or the intended purpose of the device, the significance of such a change must be assessed on a case-by-case basis.

To facilitate a harmonised judgement of the significance of changes flowcharts (see Annex) have been developed.

If a change is not a significant change in design or intended purpose under MDR Article 120(3), the implementation of such a change is therefore allowed during the transitional period. Acc. to section 3 the certificate should not be amended.

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 significant 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. Such written confirmation corrects or complements information on an existing certificate but does not represent the issuance of a "supplemented certificate" as this is prohibited as mentioned in Section 3. In case of requests from authorities the manufacturer should number such letters received from the notified body and submit them together with the certificate.

In relation to class I medical devices requiring the involvement of a notified body for the first time, manufacturers of such devices must be able to justify their decision when the changes are considered to be non-significant. The justification shall be documented and made available when requested.

This guidance document provides in its Annex several flowcharts 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"*. In particular, Chart C, which is specific to software, draws inspiration from Annex VI, Part C, section 6.5 of the MDR to identify modifications that are considered as significant change in (software) design.

The assessment of a proposed change by using the main flowchart and any of the applicable sub-charts in the Annex, is intended to assist manufacturers and notified bodies in deciding whether or not a change is to be considered significant in the design or intended purpose of the device under MDR Article 120(3).

The flowcharts are divided into a main chart and five sub-charts (A to E). There are six categorical questions in the main chart that are linked to one or more sub-charts with more detailed questions. 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" also when returning to the main chart. On the contrary, if any sub-chart

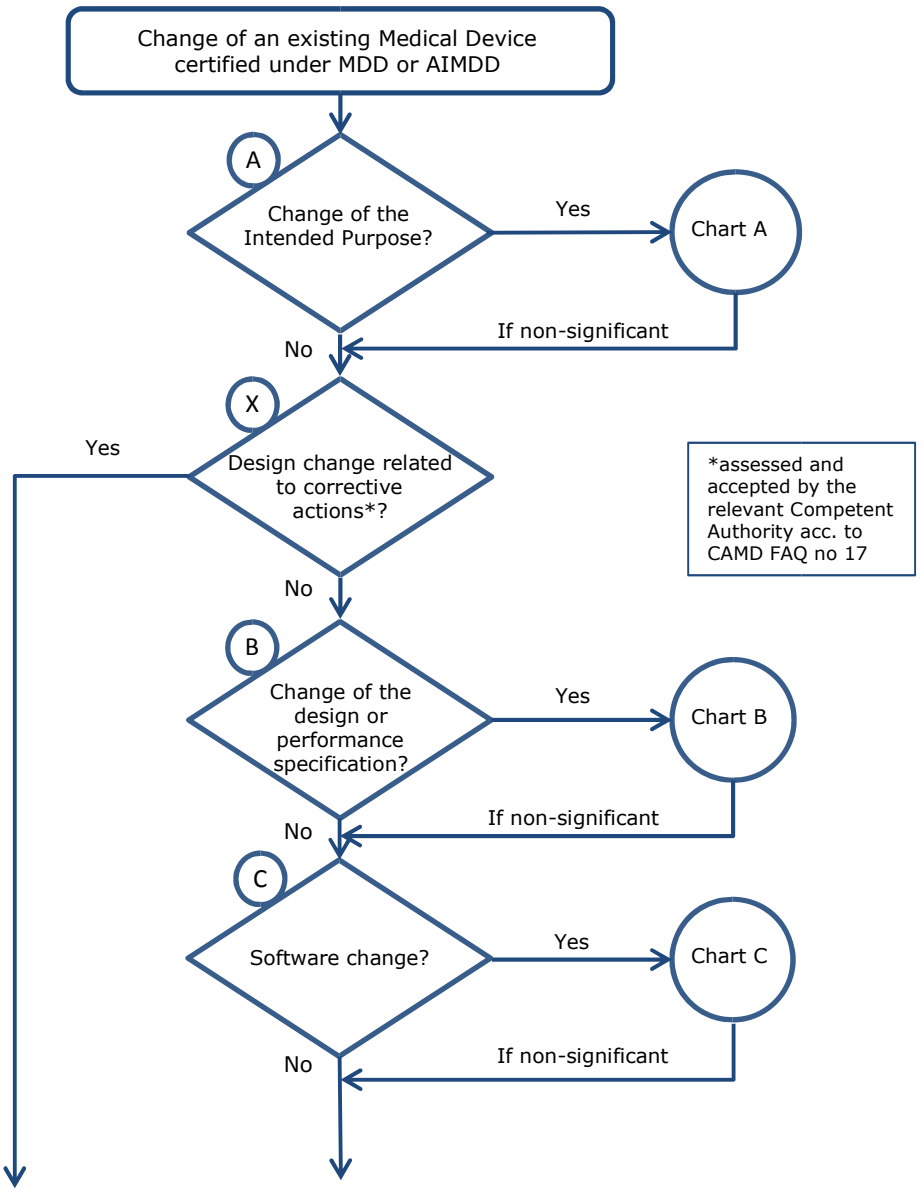
delivers the result “significant change”, the change being assessed is a “significant change in design or intended purpose” of a device according to the MDR Article 120(3).

Annex

Design Changes and Changes of the Intended Purpose

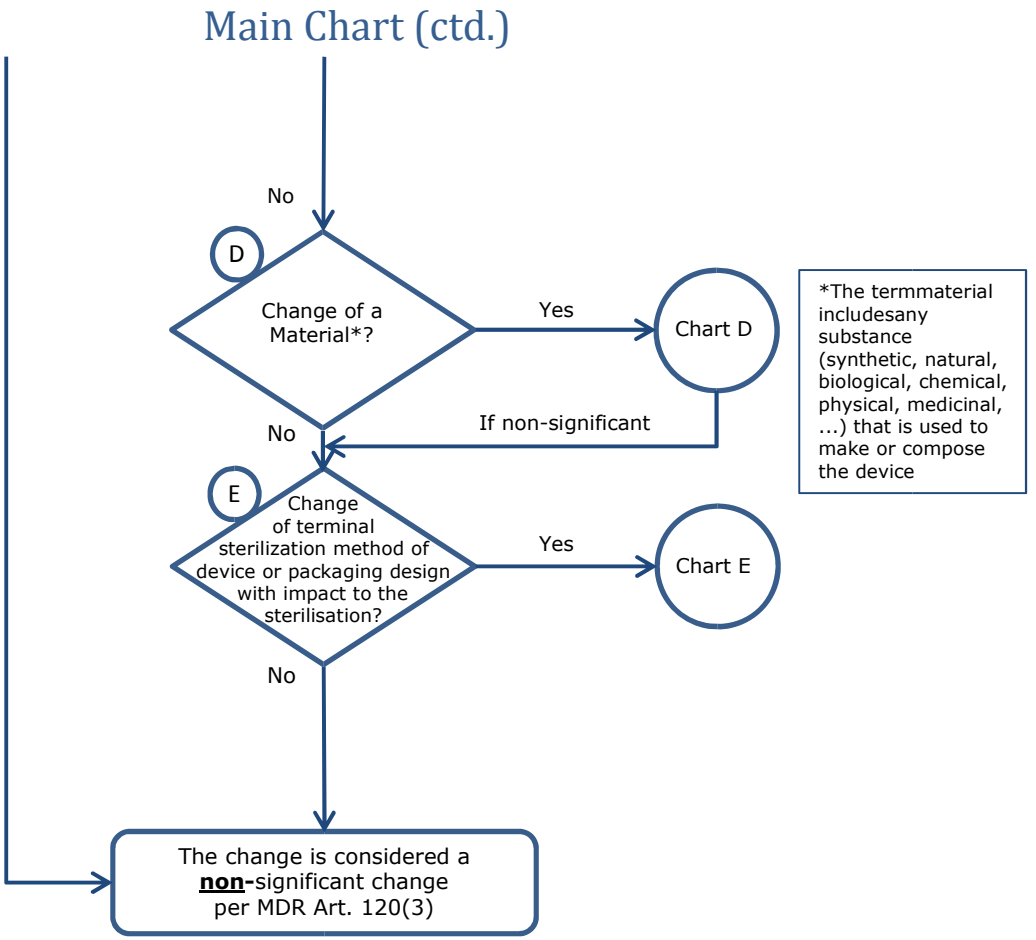
Which may be Considered "Significant" When Interpreting the First Sentence of MDR Art. 120(3)

Main Chart



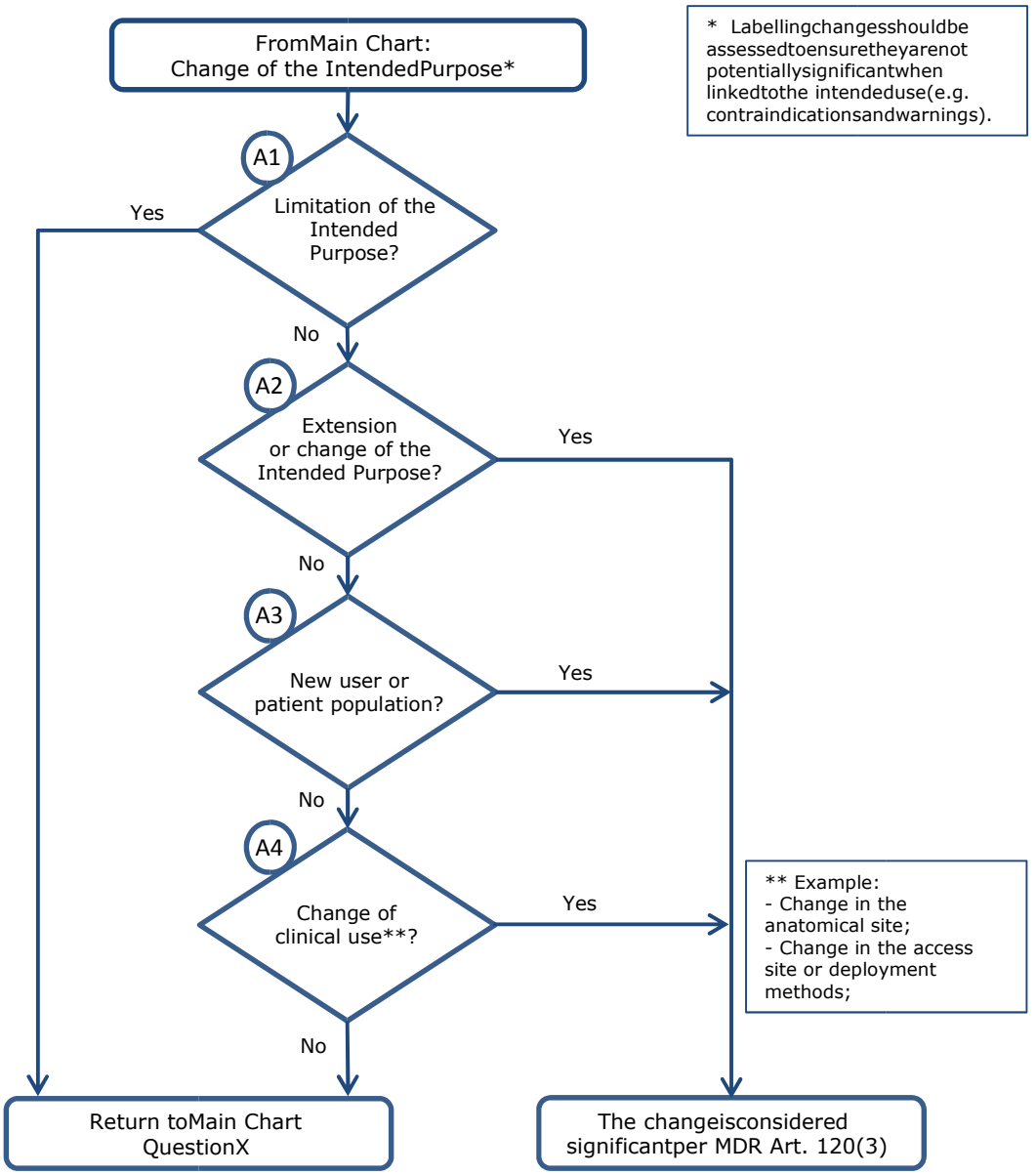
Design Changes and Changes of the Intended Purpose

Which may be Considered “Significant“ When Interpreting the First Sentence of MDR Art. 120(3)



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

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Chart B

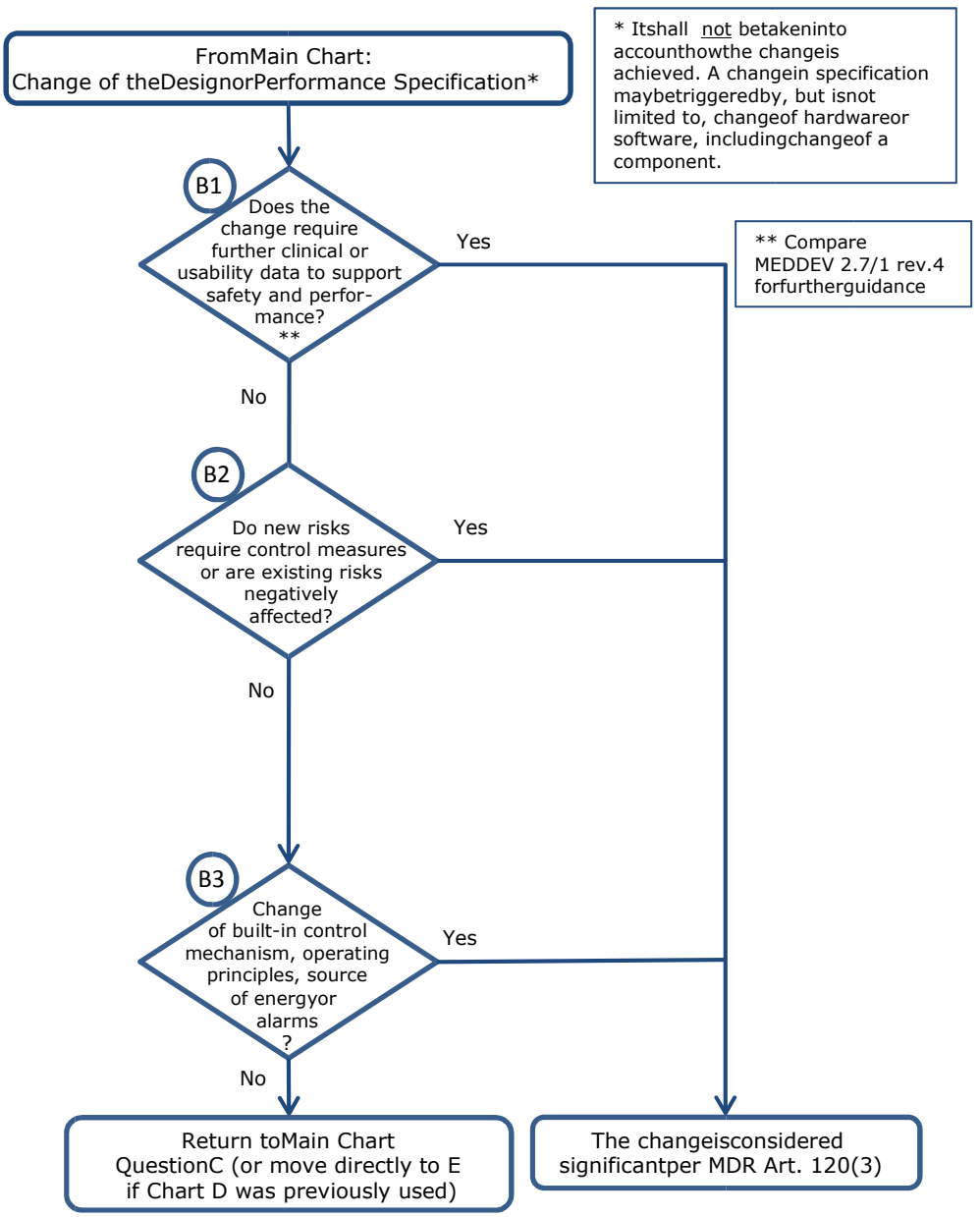

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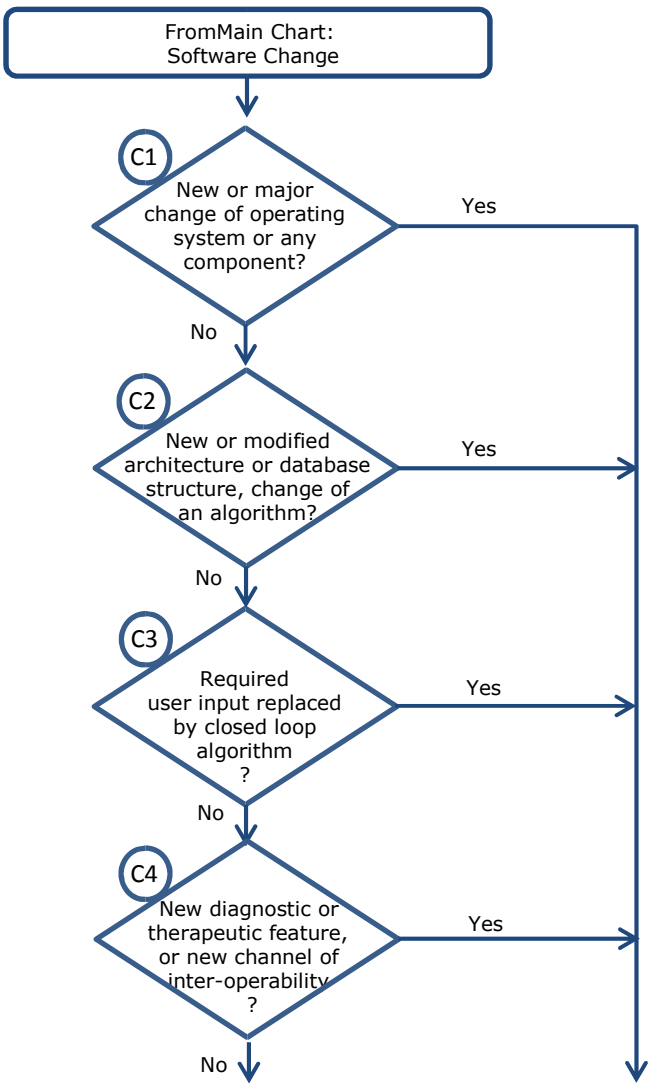
Chart C



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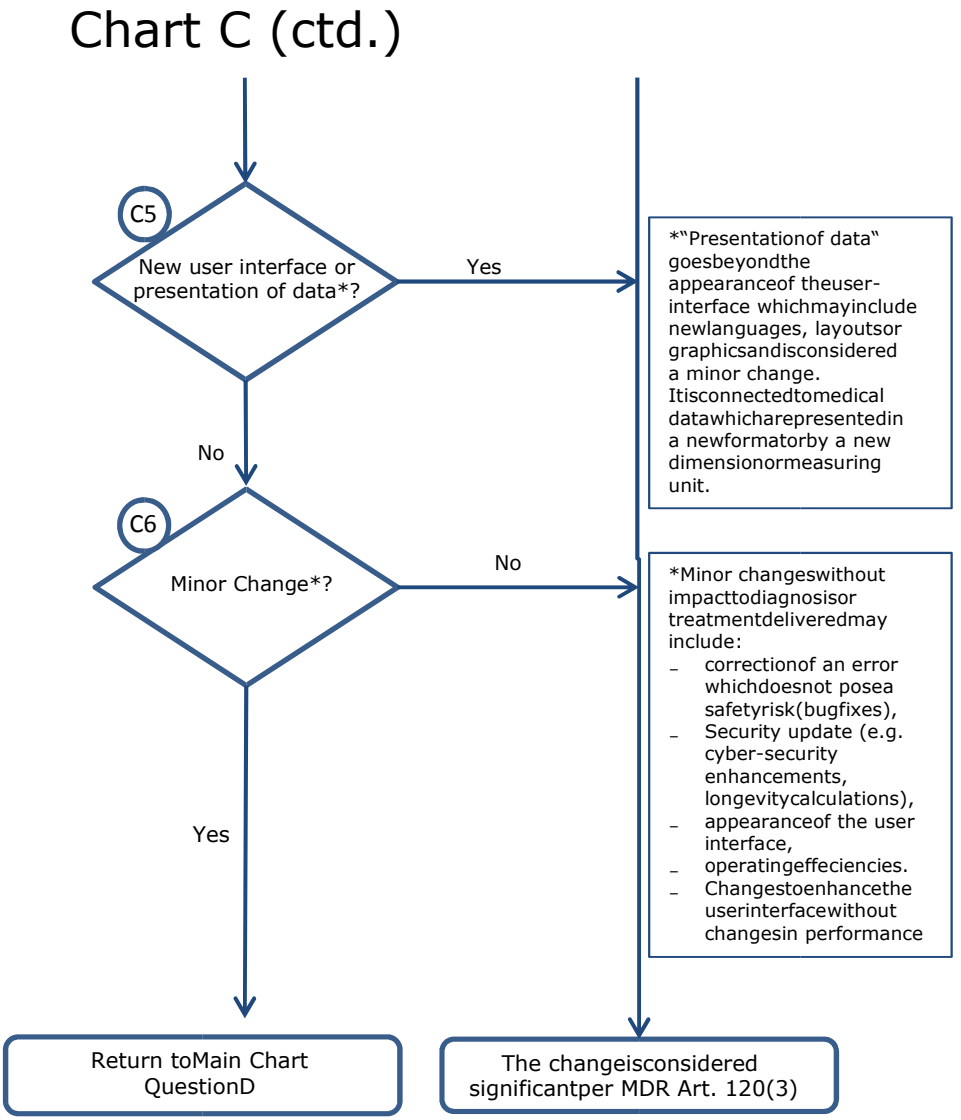

Design Changes and Changes of the Intended Purpose

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Chart D

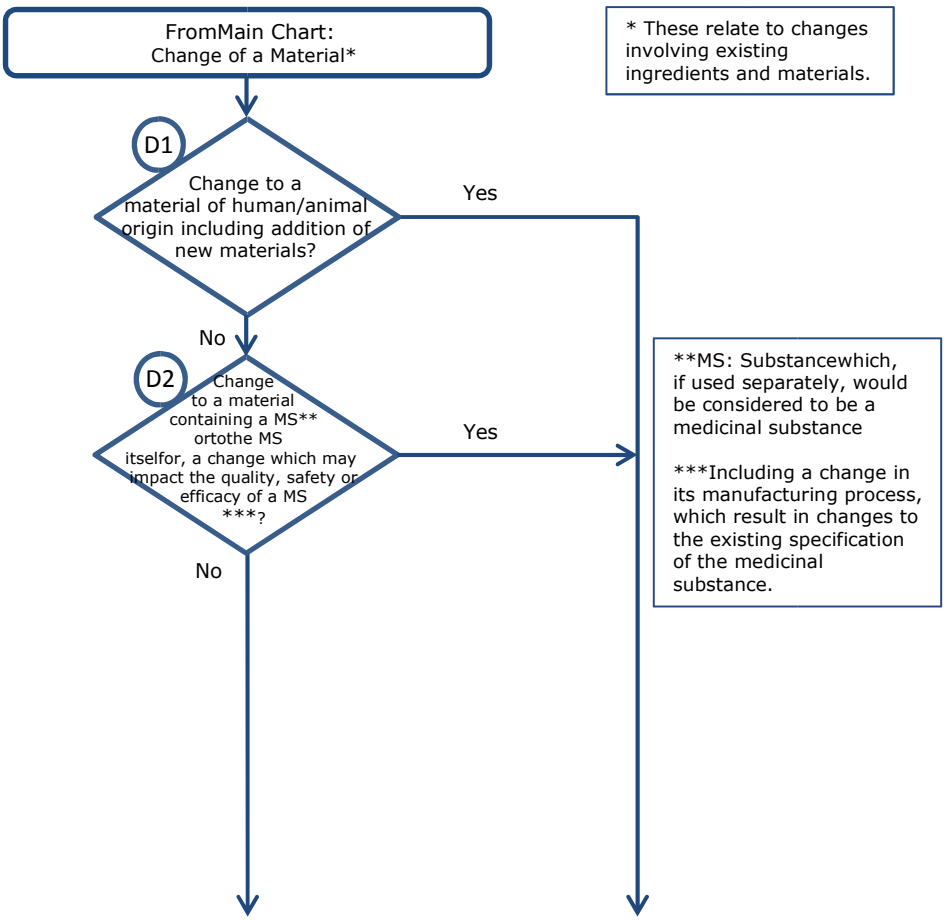

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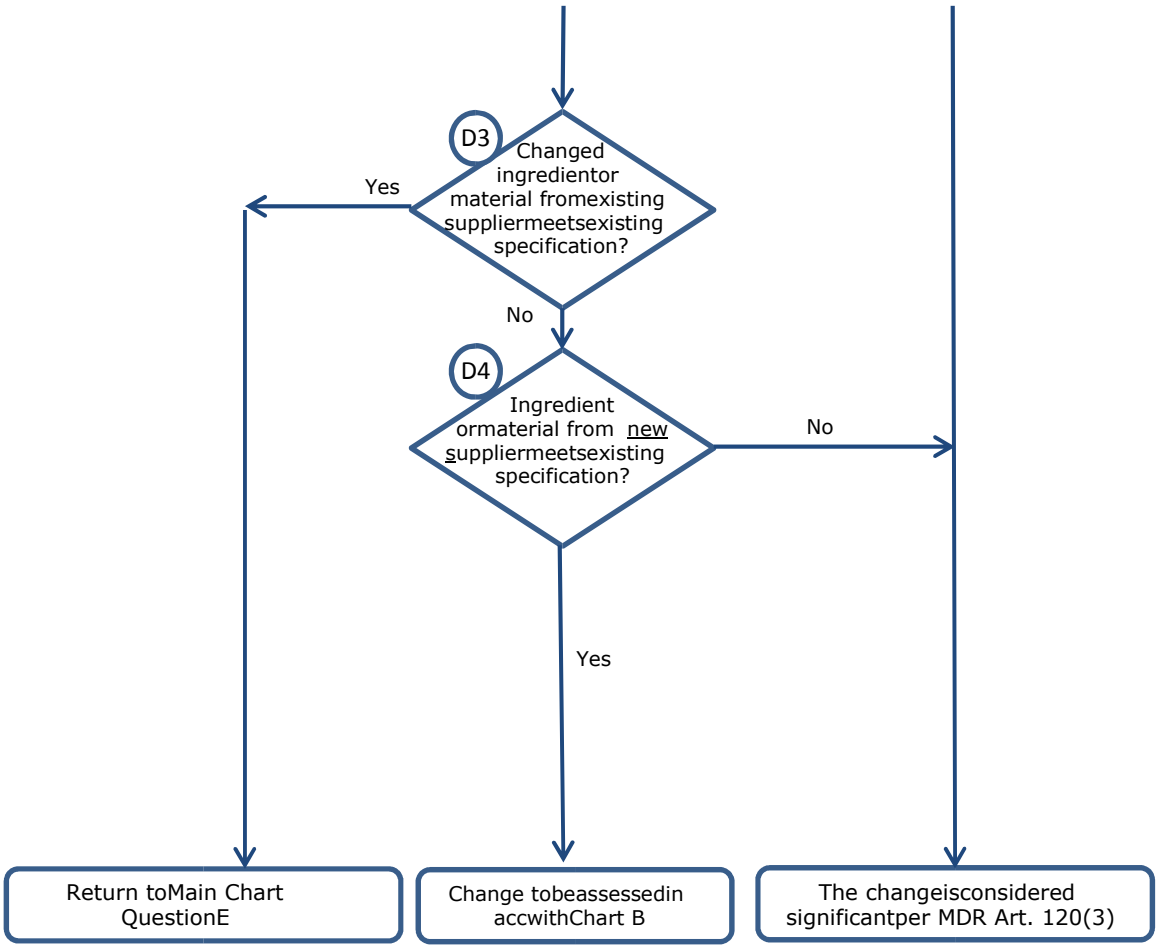
Chart D (ctd.)



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Which may be Considered “Significant“ When Interpreting the First Sentence of MDR Art. 120(3)

Chart E