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

Change of an existing Medical Device
certified under MDD or AIMDD

A
Change of the
Intended Purpose ?
Yes
Chart A
No
non-significant

X
Design change related
to an FSCA* or
Safety Update**

B
Change of the
design or performance
 specification ?
Yes
Chart B
No
non-significant

C
Software change ?
Yes
Chart C
No
non-significant

* Assessed and accepted by a Competent Authority
** Assessed and accepted by the Notified Body who issued the certificate
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.)

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Diagram:

- **D**
  - Change of an ingredient* or of a material?
    - Yes: Chart D
    - No: non-significant

- **E**
  - Change of terminal sterilization method or device or packaging design with impact to the sterilization?
    - Yes: Chart E
    - No: non-significant

The change is considered a **non**-significant change per MDR Art. 120(3)

*The term ingredient shall be used in this document in conjunction with substance based devices exclusively.
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

From Main Chart: Change of the Intended Purpose

A1

Limitation of the Intended Purpose?

Yes

A2

Extension of the Intended Purpose?

No

A3

New user or patient population?

No

A4

New way of clinical application*

Yes

No

Return to Main Chart Question X

The change is considered significant per MDR Art. 120(3)

* Example: Change of the intended purpose to deliver the coronary stent via a brachial instead of a femoral approach.
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

From Main Chart:
Change of the Design or Performance Specification*

**B1**
Will the change affect the safety, performance or usability of the device?

Yes

**B11**
Are further clinical or usability data necessary to support safety and performance of the altered device?

Yes

**B12**
Are new hazards introduced or are existing hazards negatively affected?

Yes

**B2**
Change of built-in control mechanism, operating principles, source of energy or alarms

Yes

The change is considered significant per MDR Art. 120(3)

No

Return to Main Chart Question C

* It shall not be differentiated how the change is achieved. A change in specification may be triggered by, but is not limited to, change of hardware or software, including change of a component.
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

From Main Chart: Software Change

C1

Minor Change*?

Yes

C2

New or major change of operating system?

No

C3

New or modified architecture or database structure, change of an algorithm?

Yes

No

C4

Required user input replaced by closed loop algorithm?

Yes

No
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.)

- **C5**: New feature, or new channel of inter-operability?
  - Yes
  - **C6**: New user interface or presentation of data*
    - Yes
    - Impact to diagnosis or therapy delivered?
      - Yes
      - The change is considered significant per MDR Art. 120(3)
      - No
      - Return to Main Chart Question D
    - No
  - No
- **C61**: Impact to diagnosis or therapy delivered?
  - Yes
  - The change is considered significant per MDR Art. 120(3)
  - No
- *“Presentation of data” goes beyond the appearance of the user-interface which may include new languages, layouts or graphics and is considered a minor change. The change must be connected to medical data which are presented in a new format or by a new dimension or measuring unit.*
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

From Main Chart: Change of an Ingredient or of a Material

D1
Change to a material of human/animal origin?

Yes

D2
Change to a material containing a PhSub* or to the PhSub itself**?

Yes

D3
Change of an ingredient or material was anticipated in previous conformity assessment?

Yes

*PhSub: Substance which, if used separately, would be considered to be a medicinal product

**Beyond existing specification
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.)

1 Changed ingredient or material from existing supplier meets existing specification?

No

Yes

2 Ingredient or material from new supplier meets existing specification?

No

Yes

3 Ingredient or material in contact\(^1\) with patient tissue or fluid >30d or absorbed\(^2\)?

No

Yes

\(^{1}\) with indirect or direct contact as defined by prEN ISO 10993-1:2017
\(^{2}\) surgically invasive devices only

Return to Main Chart Question E

The change is considered significant per 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 E

From Main Chart:
Change of terminal sterilization method
or device or packaging design
with impact to the sterilization

E1
Change* of
terminal sterilization
method ?
Yes

E2
Design change which
makes the device
more difficult to
sterilize** ?
Yes

E3
Change in
packaging which
affects functionality,
safety, stability or
seal integrity ?
Yes

E4
Shelf-life change validated by
using non-approved
protocols or methods ?
Yes

No

Return to Main Chart to
final determination

* Includes change from non-sterile to sterile

** Guidance on assessing changes for their impact on the effectiveness of the sterilization process is provided in the respective sterilization standards such as:
- EN ISO 11135 (Ethylene Oxide),
- EN ISO 11137-1 (Radiation),
- EN ISO 17665-1 (Mast Heat),
AESGP, the Association of the European Self-Medication Industry, is the representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe. It is composed of national associations and the main multinational companies manufacturing self-care products. AESGP is the voice of more than 2000 companies operating in the consumer healthcare sector in Europe, affiliated with AESGP directly or indirectly through the national associations. [www.aesgp.eu](http://www.aesgp.eu)

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