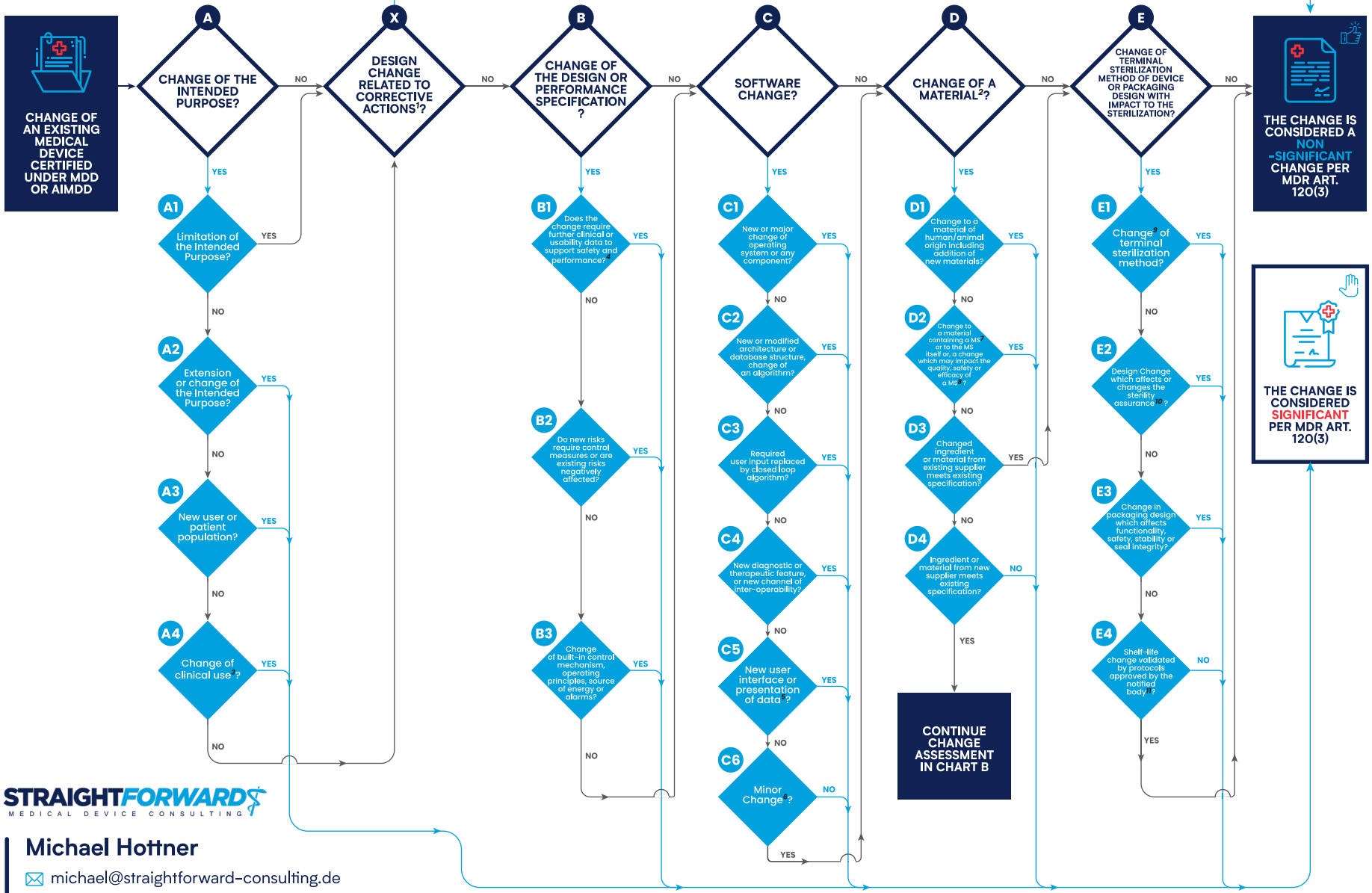
SIGNIFICANT CHANGE DECISION CHART

for evaluation of changes in design and intended purpose of a medical device under **Article 120 of the MDR (EU) 2017/745.**



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This chart is based on the MDCG guidance 2020-3.

LEGEND

MAIN CHART

1 Assessed and accepted by the relevant Competent Authority acc. to CAMD FAQ No.17

2 The term material includes any substance (synthetic, natural, biological, chemical, physical, medicinal, ...) that is used to make or compose the device.

CHART A

Labelling changes should be assessed to ensure they are not potentially significant when linked to the intended use (e.g. contra indications and warnings).

3 Example:

- Change in the anatomical site;
- Change in the access site or deployment methods;

CHART B

It shall not be taken into account 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.

4 Compare MEDDEV 2.7/1 Rev.4 for further guidance.

CHART C

5 *"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. It is connected to medical data which are presented in a new format or by a new dimension or measuring unit.

6 Minor changes without impact to diagnosis or treatment delivered may include:

- Correction of an error which does not pose a safety risk (bugfixes),
- Security update (e.g. cyber-security enhancements, longevity calculations),
- Appearance of the user interface,
- Operating effeciencies,
- Changes to enhance the user interface without changes in performance.

CHART D

These relate to changes involving existing ingredients and materials.

7 MS: Substance which, if used separately, would be considered to be a medicinal substance.

8 Including a change in its manufacturing process, which result in changes to the existing specification of the medicinal substance.

CHART E

9 Includes change from non-sterile to sterile or a change to the sterilisation method. Changes of cycle parameters under the approved quality management system are not deemed as significant in the meaning of Art. 120(3) MDR.

10 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 (Moist Heat),
- EN ISO 13408-1 (Aseptic Process).

11 In principle, an increase in shelf life can be considered non-significant (e.g. the increase is made following the completion of a real time test whose method and end-point was validated and previously assessed by the notified body).