

Technical Bulletin – Update to IAF MD 8:2020

28 January 2020

This Bulletin has been produced to ensure that certification bodies that provide Medical Device QMS (MDMS) certification services are aware of the change to IAF MD8 and of the impact it will have upon them.

This IAF document is aimed at Accreditation Bodies and the requirements that they need to take into account when assessing MDMS CBs. However, in ensuring that UKAS effectively implements all of the changes and new requirements there will, by association, be some minor changes that may impact on the systems of the certification bodies as well. Although these changes will not affect the way that the CBs approach or undertake MDMS audits, the key changes are summarised below: -

Summary of Main Changes:

- In Annex 1 - The Sterilisation Scope, 1.5, has been expanded/separated further to include 3 additional specific scope areas.
Note: It is considered that where a CB already has accreditation covering 1.5 these areas will have been assessed by UKAS as part of the overall scope and so no further assessment is needed. Where relevant, schedules will be updated to reflect the change.
- A new note has been added at the end of Table 1.7 clarifying accreditation requirements for parts and services.
This is a clarification to be taken into account for accredited certification in this scope area.
- Further clarification regarding initial approval for witnessing requirements has been added in section 7.4.5.
UKAS will need to review witnessing activities in line with this clarification and this may result in some changes to our approach to witnessing for initial assessments.
- New requirement in section 7.6 for appraisal of publicly available information published by sampling the certification body's certified manufacturers, prior to or during assessment.
This will be taken into account by UKAS during the assessment programme.

Action Required

- The changes brought about by this revision will be covered at the next scheduled head office visit.

Should you require any clarification on the subject covered by this bulletin, please contact; your Assessment Manager or Kevin Belson, Technical Manager - Kevin.Belson@ukas.com