

**MDSAP Transmittal Number:** AO 2022-02  
[Superseding MDSAP Transmittal Number 2021-04]

**Transmittal Date:** 2022/01/20

**Title:** Further Extension of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements

**Purpose:** The ongoing global spread of SARS-CoV-2 (the virus responsible for Covid-19) as well as the recent emergence of the omicron variant has resulted in the re-imposition of quarantine orders and travel restrictions that are affecting the ability of AOs to perform MDSAP audits in various countries and regions. In order to provide certainty and predictability for AOs and participating medical device manufacturers, this document further extends the interim extraordinary measures as detailed in transmittal AO-2020-10 for a further six months until 2022/06/30.

The use of these measures is strictly limited to this purpose. On-site audits may be substituted with alternative audit arrangements only where travel restrictions and social/physical distancing as result of the pandemic prevent on-site audits from occurring.

AOs are encouraged to contact their assigned APM to discuss any situation not addressed by these temporary extraordinary measures.

**Approver:** Frederic HAMELIN

**Effective Date:** 2022/01/01

**Distribution:** AOs

**Action Requested:** Apply interim measures as necessary

**Location of Documents:** TGA Connections (restricted access)

**Issued by:** MDSAP APMs