

MDSAP Transmittal Number: AO 2026-02

Transmittal Date: 2026/07/20

Title: Extension of the pilot program allowing Medical Device Organizations (MDOs) to participate in MDSAP

Purpose: The purpose of this transmittal is to inform MDSAP Regulatory Authorities (RAs), Auditing Organizations (AOs), Official Observers and Affiliate Members of updates to the voluntary pilot program allowing eligible Medical Device Organizations (MDOs) to participate in and apply for MDSAP certification.

The pilot program, initially launched on August 1st, 2025, has been extended until April 2027. The MDSAP Regulatory Authority Council (RAC) will evaluate the results of the pilot during its March 2027 meeting to determine whether to terminate the pilot and proceed with the general adoption of the revised eligibility criteria for MDOs, or to take other appropriate actions.

In addition, the participation limits for the pilot have been revised. Each AO is now limited to a maximum of 40 MDO facilities or no more than 8% of its total MDSAP facilities, whichever is smaller, thereby increasing the current participation level.

Furthermore, all AOs are required to submit, on a quarterly basis, a list of MDOs participating in the pilot program to their respective Assessment Program Manager (APM) to enable effective monitoring of participation and compliance with program limits.

Additional details are available in the updated procedure MDSAP AU P0038.002 – Eligibility of Medical Device Organizations (MDOs) to apply for MDSAP certification (attached).

Approver: Kimberly Lewandowski-Walker, RAC Chair

Effective Date: 1 August 2026

Distribution: RAs, AOs, Observers, Affiliates, Website

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