



LRQA
1330 Enclave Parkway
Suite 200
Houston, Texas 77077
United States

www.lrqa.com/us

25 May 2022

Dear MDSAP client,

RE: Notice of intent to withdraw from the Medical Device Single Audit Program (MDSAP)

We are writing to inform you that we will be withdrawing our Auditing Organisation services relating to the Medical Device Single Audit Program (MDSAP).

Following recent market developments and in the spirit of transparency, we have made the strategic business decision to exit from these services. We will however continue to provide ISO 13485 to clients both in the US and worldwide.

Although the terms of our contract stipulate that we must give 30 days' notice of our intent to withdraw services relating to the Auditing Organisation services relating to the Medical Device Single Audit Program (MDSAP), we are extending this to 60 days' notice to help ease the transition process for you. As part of this withdrawal, we will not be able to provide any further MDSAP audits for any organisation after 31 May 2022.

You must now choose an alternative Auditing Organisation – a list can be found on the <https://www.fda.gov/media/155495/download> website. We have a team in place to help with any transition activities required as you move to an alternative Auditing Organisation and we will of course work collaboratively with you and other third parties to minimise any risk of disruption to your business.

Please find below further information and next steps for you to take. If you have any queries, you may contact me at Zoe.Weber@lrqa.com

Yours sincerely,

A handwritten signature in black ink that reads 'Zoë Weber'. The signature is written in a cursive style with a large, looping initial 'Z'.

Zoë Weber

Area Service Delivery Manager, Business Assurance

YOUR FUTURE. OUR FOCUS.

For more information on LRQA visit www.lrqa.com/entities

Additional information

The Medical Device Single Audit program (MDSAP) regulator and the Group Chairman has been informed of LRQA's decision and they can provide additional support going forward.

This does not affect our services relating to ISO 9001 or ISO 13485 certification we provide.

What should you do next?

Transferral to an alternative Auditing Organisation

- Once you have a contract in place with an alternative Auditing Organisation, please let us know at LRQAclientservice.usa@lrqa.com and our team will work with that business to ensure documentation and information is transferred as smoothly as possible.
- Please note that any MDSAP current certificates will be withdrawn 60 days from the date of this letter.

What happens if you don't find an alternative Auditing Organisation before the end of the 60-day period/when LR withdraws its services or complete transfer within 60 days?

- If you have not been able to secure an alternative provider in this period:
 - We are sorry, but our services will still cease at the end of the 60-day notice period.
 - Please note that any MDSAP current certificates will be withdrawn 60 days from the date of this letter.

What happens if I am due to receive an audit from LRQA in the near future?

- As mentioned above, and agreed with the regulator, we are not able to provide audits beyond 31 May 2022.
- Once you find an alternative Auditing Organisation, please discuss with them the scheduling of your upcoming audit.