Medicines & Healthcare products
Regulatory Agency

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[redacted]
request-1105885-68c5498d@whatdotheyknow.com

26 March 2024

MHRA reference: FOI2024/00003

Dear [redacted]

Thank you for your information request, which we received on 21 March. You asked for:

> *Could you please provide a copy of the guidelines that Approved Bodies should follow when planning and conducting audits of Medical Device Manufacturers for UKCA certification under the UKMDR (2002) as amended?*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for, and we are disclosing this information in full.

Please be aware that, there isn't a single copy of guidelines that Approved Bodies use to facilitate their planning and conducting of audits. All Approved Bodies have their own procedures in place, which they use to conduct their audits of manufacturers. The way in which they conduct audits would be based on the regulations and standards, as long as the Approved Bodies meet the requirements set out in the regulations and standards.

The UK Medical Devices Regulations 2002 provides the legislative measures needed, which should be followed by all Approved Bodies. The standards that should be followed would be product specific to the medical devices that are manufactured. Some of the international standards that are generally used are shown below. However, there may also be other standards that would be required to follow.

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ISO 13485 specifies the requirements for a Quality Management System that manufacturers would need to meet at one or more stages of the life-cycle of a medical device.
ISO 13485:2016(en), Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 19011 specifies the guidelines for auditing management systems.
ISO 19011:2018(en), Guidelines for auditing management systems

ISO 14971 specifies the requirements which provide manufacturers a framework to support the management of risks associated with medical devices.
ISO 14971:2019(en), Medical devices - Application of risk management to medical devices

UK Medical Devices Regulations 2002
The Medical Devices Regulations 2002 (legislation.gov.uk)

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

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Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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