FOI 22/1218 - Ambu aScope for Cysto

REQUEST

17 November 2022

I would be most grateful if you could provide me with any publicly available evidence or information on file relating to Ambu aScope for Cysto.

The information we require includes:

- Regulatory information
    - License status within the EU and/or UK and copies of any relevant certification/proofs
    - Confirmation of the class of medical device in which the technology is approved, or expected to be approved
- Key published clinical studies relating to use in cystoscopy procedures and key information regarding on-going or recently completed studies (we will probably have most of these from our own searches but any grey lit eg. non-peer-reviewed reports that the MHRA has available would be most useful)
- Any 'Yellow Card' reports of adverse events or other information on file.

MHRA RESPONSE

22 March 2023

Dear

Thank you for your email and we apologise for delay in response.

We can confirm that the device is registered with MHRA under European medical devices regulations EU 2017/745 as a Class I sterile medical device.
Link to the publicly available registration information relating to Ambu aScope for Cysto can be found below.
https://aic.mhra.gov.uk/era/pdr.nsf/vwLkupFileRef/13708?opendocument

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU