

## FOI 24/092 - Freedom of Information request - NHS UKMDR Certification

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Thu 22/02/2024 14:29

Our ref: FOI 24/092

Dear [REDACTED]

Thank you for your request of 25 January 2024 under the Freedom of Information Act. You requested:

Please provide details of the the following:

1. How many hospitals currently hold UKCA certification under UKMDR 2002 or continue to hold CE certification under the Medical Device Directive?
2. What is the total cost to the NHS of maintaining these certifications over the past 5 years?

For question 1, the information that we hold in scope of your request is published on our website at the links below; as this information is publicly accessible it is covered by Section 21 of the Freedom of Information Act.

From our Public Access Registration Database (PARD) you can find details of registered manufacturers (there is a FAQ section on this page which provides information about what is published and how to search which you may find useful): <https://pard.mhra.gov.uk/>

For question 2, we do not hold the information you have requested for "*the total cost to the NHS of maintaining these certifications over the past 5 years?*". The only information we hold on costs are those costs associated with a registration that has been made with us, for which details of the fees can be found at this link: <https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#fees>

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

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

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely

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

-----Original Message-----

From: [REDACTED]  
Sent: Thursday, January 25, 2024 5:41 PM  
To: MHRA Customer Services <[MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)>  
Subject: FOI 24/092 - Freedom of Information request - NHS UKMDR Certification

You don't often get email from [REDACTED]  
[REDACTED]

Dear Medicines and Healthcare Products Regulatory Agency,

Please provide details of the the following:

1. How many hospitals currently hold UKCA certification under UKMDR 2002 or continue to hold CE certification under the Medical Device Directive?
2. What is the total cost to the NHS of maintaining these certifications over the past 5 years?

Yours faithfully,

[REDACTED]

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Please use this email address for all replies to this request:

[REDACTED]