FOI 24/171 - Freedom of Information Request - Medical Device Registration

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

Tue 19/03/2024 09:37

To [redacted]

1 attachments (39 KB)

Product registrations by month Jan 2021 to Jan 2024.xlsx;

FOI 24/171

Dear [redacted]

Thank you for your email of 21 February 2024, where you asked:

> *Under the Freedom of Information Act 2000, can you provide the following information:*
> *The total number of MHRA registrations for each of the following:*
>
> 1. *Medical Devices to UKCA by class*
> 2. *Medical Devices to EU MDR by class*
> 3. *Medical Devices to EU MDD by class*
> 4. *IVDs to UKCA by category*
> 5. *IVDs to EU IVDR by class*
> 6. *IVDs to EU IVDD by category*
> 7. *Digital Health Technologies (inc. SaMD) to UKCA by class/category*
> 8. *Digital Health Technologies (inc. SaMD) Health Technologies (inc. SaMD)to EU MDR by class*
> 9. *Digital Health Technologies (inc. SaMD) to EU IVDR by class*
> 10. *Digital Health Technologies (inc. SaMD) to EU MDD by class*
> 11. *Digital Health Technologies (inc. SaMD) to EU IVDD by category*

Please see the attached spreadsheet that contains the answers to questions 1 to 6.

For questions 7 to 11, we can explain that we don't currently capture the SaMD details in the registrations system based on GMDN alone. In order to locate this information, we would need you to provide further details of what you require from the GMDN CT codes.

When we receive your clarification, we will be able to proceed with a new request for this information.

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

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Wednesday, February 21, 2024 12:36 PM
To: [redacted]
Subject: Freedom of Information Request - Medical Device Registration

You don't often get email from [redacted]

Dear Sir/Madam,
Under the Freedom of Information Act 2000, can you provide the following information:
The total number of MHRA registrations for each of the following:

1. Medical Devices to UKCA by class
2. Medical Devices to EU MDR by class
3. Medical Devices to EU MDD by class
4. IVDs to UKCA by category
5. IVDs to EU IVDR by class
6. IVDs to EU IVDD by category
7. Digital Health Technologies (inc. SaMD) to UKCA by class/category
8. Digital Health Technologies (inc. SaMD) Health Technologies (inc. SaMD)to EU MDR by class
9. Digital Health Technologies (inc. SaMD) to EU IVDR by class
10. Digital Health Technologies (inc. SaMD) to EU MDD by class
11. Digital Health Technologies (inc. SaMD) to EU IVDD by category

Thank you and best regards,
[redacted]