FOI 23/341 - UK Conformity Assessment (UKCA) certificates issued for medical devices and invitro diagnostic medical devices to date, broken down by group

MHRA RESPONSE
1 June 2023

Dear

Thank you for your email.

Please find response to the above FOI request.

a. **Under the Freedom of Information Act 2000, can you provide the following information:**

The total number of UK Conformity Assessment (UKCA) certificates issued for medical devices and invitro diagnostic medical devices to date, broken down by group.

Since January 2021 designated UK Approved Bodies have been able to issue UKCA certificates for medical devices and IVDs that require certification by a conformity assessment body prior to the device being placed on the GB market. Low risk medical devices and IVDs do not require Approved Body certification. Approved Bodies issue certificates attesting that the manufacturers Quality Management System complies with regulatory requirements as well as issuing certificates that confirm the devices themselves comply with the requirements. Both types of certificates are represented in the figures below. Certificates issued by an Approved Body generally cover more than one device, so the number of certificates does not equate to the number of devices that have been certified.

Table 1

	General Medical Devices (Part II of UK MDR 2002)	**Active Implantable Medical Devices (Part III of UK MDR 2002)**	**In Vitro-Diagnostic Medical Devices (Part IV of UK MDR 2002)**	**Total**
January – December 2021	112	0	0	112
January – December 2022	336	8	3	347

January 2023 – to 13th April 2023*	138	0	2	140
Total	586	8	5	**599**

*Our most recent data only covers to April 2023.

b. **Under the Freedom of Information Act 2000, can you provide the following information:**

The total number of medical devices and invitro diagnostics medical devices in the U.K which are registered with the MHRA, including those that are UKAB certified and those that are self-declared to U.K. MDR.

Table 2

	General Medical Devices (Part II of UK MDR 2002)	**Active Implantable Medical Devices (Part III of UK MDR 2002)**	**In Vitro-Diagnostic Medical Devices (Part IV of UK MDR 2002)**	**Total**
UK approved body certified	187	1	1	189
Self-declared MDR 2002	169	0	1	170
Total	356	1	2	359

*Our most recent data only covers to April 2023.

To note that registered does not necessarily mean it has been placed on the market, just that it can be.

The data in table 2 indicates registered devices at GMDN level. For details of registered products, please see the attached document. It only includes registrations from 2021.

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