



Medicines & Healthcare products Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: FOI2026/01080

20 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 17 September. You wrote:

If possible, please could the MHRA provide answers to the following:

- 1. The number of safety incidents relating to i) SaMDs (Software as a Medical Device) and ii) AlaMDs (Artificial Intelligence as a Medical Device) reported to date through the MHRA's Yellow Card system.*
- 2. A full list of all providers of SaMDs and AlaMDs the MHRA has registered in each of its risk based classification categories*

MHRA Response

We confirm that we hold some of the information you have requested.

With regard to part (1)(i) of your request, the MHRA codes medical devices reported through the Yellow Card scheme using the Global Medical Device Nomenclature (GMDN). GMDN is a system of internationally agreed generic descriptors used to identify medical device products.

To identify reports relating to Software as a Medical Device (SaMD), the MHRA searched UK adverse incident reports recorded under the following software-related GMDN Collective Terms (CTs): CT1651 (Software); CT2673 (Consultative patient-use software), CT2674 (Non-consultative patient-use software) and CT2694 (Patient-use software); CT910 (Interpretive software IVDs), CT944 (Software IVDs) and CT1250 (Analyser software IVDs); CT1448 (Information system software) and CT169 (Operating system software); CT1976 (Diagnostic x-ray system software), CT1977 (Dental x-ray system software), CT2669 (Radiological software), CT2670 (Therapeutic radiological system software) and CT2671 (Picture Archive and Communication System (PACS) software); and CT2884 (Physiological monitoring/measuring device software).

Based on this search strategy, as of 25 September 2026, the MHRA had received 694 UK adverse incident reports relating to Software as a Medical Device (SaMD).

When reviewing adverse incident data, please note:

The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues. Reports do not necessarily represent individual patients, as individuals may submit multiple reports relating to the same issue at any time after the event occurred. Where possible, multiple reports relating to the same event are linked. However, as reporters are not required to complete all fields, we cannot always be certain enough to identify and link every duplicate report.

It should also be noted that this information may include recognised complications associated with the use of medical devices and does not necessarily indicate a fault with any particular device. In addition, the figures provided may include reports where the incident information has been obtained from published literature.

The figures are accurate at the time they were extracted from our database. Minor changes may occur where additional information is subsequently received from the reporter. The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device. Such events may be attributable to other factors, including underlying patient conditions, user factors, procedural factors, or other circumstances unrelated to the performance of the device.

The data provided should therefore not be regarded as a summary of known or proven adverse reactions, nor should it be used to determine the incidence of an adverse event. A report's inclusion in the database does not constitute proof of a causal association between the device and the reported event.

With regard to part (1)(ii) of your request relating to Artificial Intelligence as a Medical Device (AIaMD), the MHRA does not currently maintain a specific category, identifier or coding system for AI-enabled medical devices within the Yellow Card database. Medical devices are categorised according to their intended purpose and function using GMDN terminology, rather than whether they incorporate artificial intelligence functionality. As a result, it is not possible to conduct a search that would reliably identify all adverse incident reports associated specifically with AI-enabled medical devices. Consequently, we do not hold information in a recorded form that would allow us to provide the number of safety incident reports relating specifically to AIaMDs.

While some AI-enabled medical devices may be captured within software-related GMDN categories, the presence of a software-related GMDN code does not indicate whether a device incorporates artificial intelligence functionality. Equally, some AI-enabled medical devices may not be identifiable solely from the GMDN code assigned to a report. Therefore, the attached SaMD data should not be interpreted as representing all AI-enabled medical devices reported to the MHRA.

Should you be interested in a particular AI-enabled product, manufacturer, or device brand, you may wish to submit a further Freedom of Information request identifying the specific product(s) concerned. Where sufficient information is provided to identify a particular device, the MHRA may be able to undertake further searches using device-specific information held within individual reports.

With regard to part (2) of your request, the MHRA registration database does not currently capture whether a registered medical device is specifically Software as a Medical Device (SaMD) or Artificial Intelligence as a Medical Device (AIaMD) in a manner that would allow a complete and reliable extraction of all such devices by risk classification.

Medical devices are registered using information provided by manufacturers and may be recorded under a range of device categories. The registration database does not contain a dedicated searchable field identifying whether a device is a SaMD or incorporates artificial intelligence functionality. As a result, the MHRA is unable to identify all providers of SaMDs and AlaMDs, or produce a definitive list of such providers broken down by risk classification, from existing registration data.

While the MHRA holds information relating to registered medical devices, the information requested is not held in a recorded form that would enable a complete and reliable response to be produced. Consequently, we are unable to provide the information requested.

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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