



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00965**

11 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 27 August. You wrote:

This is a request for information under the Freedom of Information Act 2000. I would like to request information on the AI Assisted Discharge Summary (AADS) tool that's hosted on the Federated Data Platform (FDP). This tool was piloted at Chelsea and Westminster Hospital NHS Foundation Trust and was recently certified by the MHRA as a Class I medical device (GMDN Code: 61087) for official use as an NHS tool.

1) In the latest minutes from the NHS England Data Transformation Check and Challenge Group, published in April 2026, it was reported that "The group reviewed the FDP action log and noted progress across several areas. It was confirmed that the DPIA for the AI Assisted Discharge Summary remained on track but could not be finalised until the product reaches pilot stage"

Can you please provide me with the DPIA for the AADS.

Source for Q 1: <https://www.england.nhs.uk/long-read/tra...<https://www.england.nhs.uk/long-read/transformation-check-and-challenge-group-meeting-minutes-13-april-2026/>>

2) Can you please provide me with the registration/certification date for the AADS device by the MHRA? Can you also please provide me with the dates the tool was being officially piloted at Chelsea and Westminster.

3) In regards to the self certification of the AADS the manufacturer would have compiled technical documentation, implemented a Quality Management System (QMS) and created a Declaration of Conformity. The manufacturer must also must prove their device meets the Essential Requirements (ERs) of the UK Medical Devices Regulations 2002.

Can you please provide me with this technical documentation, including the Quality Management System (QMS) documentation which may consist of policies, standard operating procedures, risk assessments, approval procedures, decision logs, software validation, and post-market surveillance procedures. Can you also please provide me with the Declaration of Conformity, and the proof that the manufacturer met the Essential Requirements (ERs) of the UK Medical Devices Regulations 2002.

MHRA Response

Following a detailed assessment of your request, we have established that the information you requested is not held by this Agency.

The MHRA does not grant clearance or approval for medical devices, outside of [exceptional circumstances](#). Registration of medical devices with the MHRA (the UK Competent Authority) does not represent any form of clearance, accreditation, certification, approval, or endorsement by the MHRA. The manufacturer holds the legal responsibility for obtaining the necessary certification and registering their medical devices with MHRA. Higher risk medical devices are assessed and approved by Approved Bodies in the UK or Notified Bodies in the EU.

Below, we address each of your questions separately.

1. In the latest minutes from the NHS England Data Transformation Check and Challenge Group, published in April 2026, it was reported that “The group reviewed the FDP action log and noted progress across several areas. It was confirmed that the DPIA for the AI Assisted Discharge Summary remained on track but could not be finalised until the product reaches pilot stage”

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MHRA doesn't routinely have access to Data Protection Impact Assessments relating to medical devices. These documents don't form part of the requirements of UKMDR 2002.

2. Can you please provide me with the registration/certification date for the AADS device by the MHRA? Can you also please provide me with the dates the tool was being officially piloted at Chelsea and Westminster.

The information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

In the registration database MHRA has a registration date for this device, information is not held on when the tool was piloted. You can find the manufacturers information registered with MHRA at on the Public Access Registration Database [PARD](#).

You can use the Advance Search in PARD to search by Global Medical Device Nomenclature (GMDN®) Term in the Medical Device Type field.

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Can you please provide me with this technical documentation, including the Quality Management System (QMS) documentation which may consist of policies, standard operating procedures, risk assessments, approval procedures, decision logs, software validation, and post-market surveillance procedures. Can you also please provide me with the Declaration of Conformity, and the proof that the manufacturer met the Essential Requirements (ERs) of the UK Medical Devices Regulations 2002.

Please note that the MHRA does not itself assess or approve medical devices placed on the UK market, please see the guidance regarding the [UKCA mark and Conformity Assessment Bodies](#).

Information with regards to manufacturers of Class I devices and their responsibilities are outlined here: [Guidance on Class I medical devices](#)

In relation to the manufacturer's technical documentation, Quality Management System documentation, Declaration of Conformity, Essential Requirements checklist, software validation records, risk assessments, decision logs, and post-market surveillance procedures, these are records, documents, SOPs that would, as stated, be held by the manufacturer as part of its own regulatory compliance documentation to meet regulatory requirements.

The MHRA may hold certain information about a device where it has been submitted to the Agency for a specific regulatory purpose, such as registration, vigilance, compliance, enforcement, clinical investigation, or other regulatory activity.

However, MHRA's role as regulator does not mean that it routinely holds a manufacturer's full technical file or quality management documentation for every device placed on the market.

In this circumstance, the requester may wish to seek the information directly from the manufacturer, who is responsible for maintaining the documentation necessary to demonstrate conformity with the applicable requirements of the UK Medical Devices Regulations 2002.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

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.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>