



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

[MHRA Website](#)

Our Ref: **FOI2026/01033**

09 October 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 11 September. You wrote:

Thank you for your response to FOI2026/00903. Three follow-up questions, please, as a new request under the Freedom of Information Act 2000:

- 1. Does GMDN code CT269 or CT299 capture monitor-defibrillators? If not, please provide the equivalent figures under the correct code.*
- 2. Please provide the IMDRF Annex A breakdown, by year, for all 86 fatal reports 2023–2025 – not just the first 10 reports per year.*
- 3. Are the 2025 figures (336 reports; 29 fatal) final, or still provisional?*

MHRA Response

We confirm that we hold the information you have requested.

You enquired whether Global Medical Device Nomenclature (GMDN) Collective Term (CT) codes CT269 (External Defibrillators) and CT299 (Public Access Defibrillators) capture monitor-defibrillators and, if not, to provide the equivalent figures under the correct code.

We can confirm that monitor-defibrillators are captured within CT269 – External Defibrillators. Specifically, CT269 includes GMDN term 17782 – Physiologic-monitoring defibrillation system, which is the classification used for monitor-defibrillators.

The search undertaken for FOI2026/00903 identified defibrillator-related reports using the following GMDN classifications, which were selected as they encompass external, automated external, manual and monitor-defibrillator device types:

- CT269 – External Defibrillators
 - **17782 Physiologic-monitoring defibrillation system**
 - 35972 Automatic external defibrillator
 - 37805 Semi-automated external defibrillator
 - 37806 Manual external defibrillator
 - 48048 Rechargeable professional automated external defibrillator
 - 48049 Non-rechargeable professional semi-automated external defibrillator
 - 48050 Home automated external defibrillator

- CT299 – Public Access Defibrillators
 - 47910 Non-rechargeable public semi-automated external defibrillator
 - 48045 Rechargeable public semi-automated external defibrillator
 - 48046 Rechargeable public automated external defibrillator
 - 48047 Non-rechargeable public automated external defibrillator

As monitor-defibrillators are already captured within CT269, no additional searches or revised figures are required.

Additionally, you requested the IMDRF Annex A breakdown by year for all fatal reports received between 2023 and 2025.

To identify fatal reports, we extracted all adverse incidents reports relating to defibrillators where either:

- Death was recorded as the reported patient outcome; or
- IMDRF Annex F code F02 (Death) had been assigned.

A further extraction of the data ran on the 1st October 2026, identified **96** adverse incidents reports with a recorded fatal outcome between 1 January 2023 and 31 December 2025, of which 20 reports were from 2023, 38 reports from 2024 and 38 reports from 2025.

The previous response identified 86 fatal reports. The increase reflects the dynamic nature of the MHRA adverse incident database. Figures can change where additional information is received from reporters, existing reports are updated, duplicate reports are identified and linked, or further case assessment results in additional coding being applied.

The accompanying **Annex 1** tables provide the IMDRF Annex A code breakdowns for all fatal reports identified during this extraction. The document contains:

- *Table 1. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports Received Between 1 January 2023 and 31 December 2023*
- *Table 2. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports Received Between 1 January 2024 and 31 December 2024*
- *Table 3. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports Received Between 1 January 2025 and 31 December 2025*

Please note that individual reports may be assigned more than one IMDRF Annex A code where multiple device problems were identified during assessment. As a result, the total number of IMDRF Annex A codes shown within the breakdown may exceed the total number of fatal reports.

Furthermore, you enquired whether the 2025 figures (336 reports;29 fatal) are final or provisional.

The figures provided in our previous response were accurate at the time they were extracted from the MHRA adverse incident database. However, the database is dynamic and therefore the figures should be considered a snapshot of the data held at that time.

For example, the previous response identified 478 reports in 2023, 595 reports in 2024 and 336 reports in 2025, including 86 reports with a recorded fatal outcome across the period.

A subsequent extraction identified **486** reports in 2023, **595** reports in 2024 and **496** reports in 2025, including **96** reports with a recorded fatal outcome across the period.

Minor changes in the figures may occur where:

- Additional reports are received;
- Existing reports are updated following receipt of further information;
- Duplicate reports are identified and linked; or
- Further case assessment results in additional coding being applied.

Accordingly, the figures are not considered final and may change over time as the database is updated. All figures provided in this response are accurate as of the date which the data was extracted.

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. An individual may submit a report at any time after an event and may submit multiple reports relating to the same incident. Where possible, duplicate reports are identified and linked. However, because reporters are not required to complete every field, it is not always possible to identify all duplicate reports with certainty.
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- The numbers may include reports where the incident has been taken from published literature.
- The inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. The data provided, therefore, is not a summary of known or proven adverse reactions to the device and must not be interpreted and used as such.

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/>

Annex 1

Data extraction date: 1st October 2026



Annex 1
Breakdown.pdf