# Medical devices incident reports: an Italian experience

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## Background and importance

Dispovigilance is the Italian Ministry of Health's database supporting the National Vigilance Device Network since October 2022. It is an essential tool in the reporting system for serious and non-serious incidents, as well as safety actions related to medical and in vitro diagnostic devices (MDs and IVDs).


The National Classification of Medical Devices (CND) groups MDs into homogeneous categories for similar diagnostic and/or therapeutic intervention. The European Medical Device Nomenclature (EMDN), established by Regulations 2017/745 and 2017/746, is based on the Italian CND. The Regulations also classify MDs into different risk classes.

### Aim e objectives

The purpose was to investigate MDs involved in incidents that occurred at an Italian hospital, in order to provide real-world evidence.

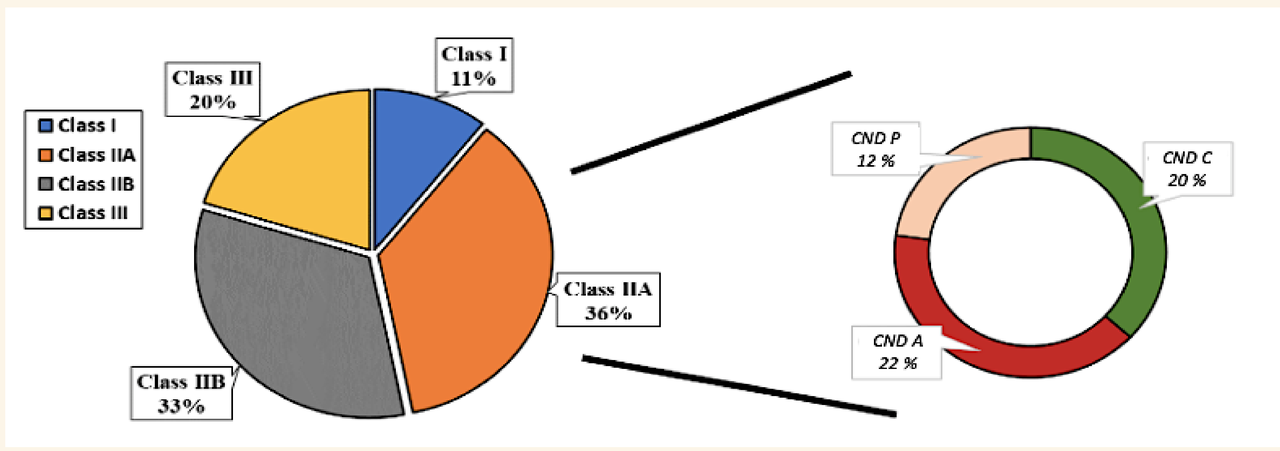
## Materials and methods

This study was performed on incident reports collected through Dispovigilance between January 2022 and December 2024. CND, risk class (I, IIA, IIB, III) and reporter were analysed.

## Results

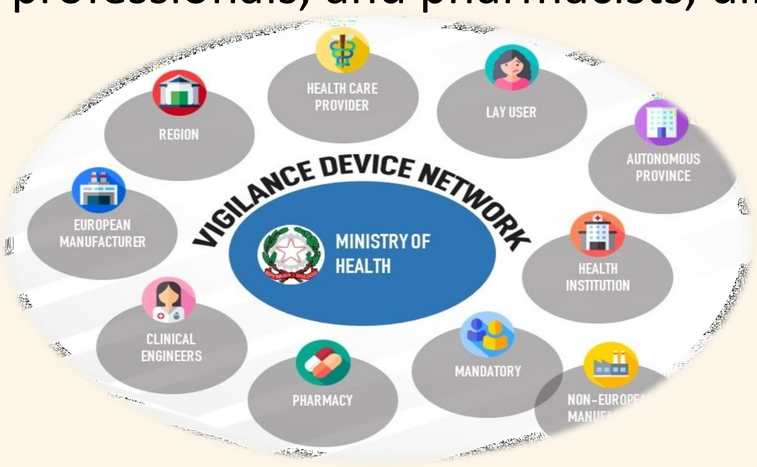
A total of 104 reports were collected: 17 (16%) originated in 2022, 36 (35%) in 2023, and 39 (38%) in 2024. According to the CND, the most frequently reported MDs belonged to 'A, Devices for Administration, Withdrawal Collection' (23 cases, 22%), 'C, Cardiocirculatory System Devices' (21 cases, 20%), and 'P, Implantable Prosthetic and Osteosynthesis Devices' (13 cases, 12%).

Regarding risk classification, 10 medical devices were classified as Class I, 34 as Class IIA, 31 as Class IIB, and 19 as Class III.
The majority of incidents were reported by clinicians (40 cases), followed by nurses (16) and pharmacists (7 cases, all occurring between 2022 and 2024).




## Conclusion and relevance

Analysis shows an increasing trend in reports from 2022 to 2024, likely due to the introduction of Dispovigilance, although underreporting persists, especially for low-risk devices. Most reports concern medium- and high-risk devices. According to the CND classification, categories C and P are frequently reported, possibly reflecting greater focus on these high-risk devices. Clinicians are the main reporters, followed by nurses, healthcare professionals, and pharmacists, directly involved in device management.




Notably, pharmacist reports have declined sharply over time, indicating increased awareness and targeted training among primary device users on the front lines of reporting. This study underscores the essential role of medical device vigilance.

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