

Public summary of results

Article 93(8) MDR/Article 88(8) IVDR:

The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 100 MDR/ Article 95 IVDR.

Title: Summary of the results of Member States' assessment and review of the functioning of market surveillance activities according to Article 93(8) of Regulation (EU) 2017/745 and Article 88(8) of Regulation (EU) 2017/746 for the period 2022-2025.

Reporting authority

Name of authority responsible for market surveillance reporting under the MDR/IVDR:

Danish Medicines Agency (DKMA)

Axel Heides Gade 1

2300 Copenhagen

DK – Denmark

Key Achievements at National Level

List relevant observations or trends you have observed at national level and relevant improvements and/or projects achieved/implemented during the reporting period:

- Improved economic operator compliance following inspections
- Conducted several effective risk-based national inspection campaigns of targeted groups of economic operators
- Data collection for risk-based selection of economic operators for inspection
- Increased the number of authorised medical device inspectors and the number of inspections performed during the reporting period
- Contentious development of a systematic data driven and risk-based approach to handle increased number of incident reports
- Improved collaboration with the healthcare system, particularly through the project 'Closer to the Healthcare System'. Development of informational materials, including brochures, posters, and presentations. Proactively contract with the offer of free presentations targeting hospitals, municipalities, and educational institutions
- Better opportunity for reporting suspected illegalities
- Development of principles and internal procedures for market surveillance cases
- Focus on challenges with adhesives
- Strengthened cooperation with the Danish Customs Agency
- Closer internal collaboration between the Inspectors and Market Surveillance assessors

- Collaboration with a Danish public entity “Sterilcentralen” regarding reprocessing of reusable medical devices and national guidelines
- MDR information campaigns at universities focusing on obligations with regards of medical devices software
- MDR information campaigns targeting both the Danish public service sector and private economic operators
- National targeted activity towards economic operators with products without an intended medical purpose in scope of Annex XVI

Coordination and cooperation on market surveillance

List any coordination or cooperation activities your authority participated in during the reporting period.

These may include joint actions or initiatives at EU, national, or international level — such as coordinated activities between Member States, cross-agency efforts within your country, or participation in initiatives like JACOP, joint inspections, or EU-funded projects.

- Participating and hosting joint inspections as part of the 'Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices 2.0 (JAMS 2.0)' WP6: Inspection
- Development of training material on post-inspection processes under JAMS 2.0 WP6
- Participation in 'Joint Actions on Compliance of Products', Product Specific Activity 1 and Product Specific Activity 2. Aiming to enhance transparency and support cross-border regulatory awareness and cooperation at EU level
- Participation in and chairing of the MDITF (Medical Device Inspectors Task Force)
- Participating and co-leading the JAMS 2.0 WP5: Signal detection and Vigilance
- Formalized collaborations with Brazil, Mexico, China, Canada, USA and India