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JAMS 2.0

JAMS 2.0 Work Package 6

D6.2: Summary on the performance of Joint Inspections of Manufacturers

Date: 10 November 2025

Version: 1

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This document is part of the project JAMS 2.0, n°101127889 which has received funding from the European Union's Health Program. (Co-)Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

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I. Foreword

The Joint Action on reinforced Market Surveillance of medical devices and in vitro diagnostic medical devices 2.0[1,2] (JAMS 2.0) is a joint action co-funded by the European Union as part of the EU4Health programme[3]. Initiated in November 2023, it ends in October 2026 and aims to reinforce the market surveillance of medical devices between Member States and to harmonise approaches across the European Union.[4]

This project is divided into four technical work packages (WP) covering different aspects of market surveillance. Each WP provides opportunities under which information, best practices, knowledge and resources will be shared between national Competent Authorities (CA):[5]

- WP 1-4: Coordination, dissemination, evaluation and sustainability;
- WP 5: Signal detection and Vigilance;
- WP 6: Inspection;
- WP 7: Market Surveillance Campaigns;
- WP 8: MD/IVD University.

The goal of WP 6 is to harmonise the inspection activities throughout the Union market[6]. It is articulated around three main objectives:[7]

- To develop a consistent framework to carry out joint inspections;
- To execute joint inspections according to the developed framework;
- To train inspectors according to the framework.

To achieve these objectives, four main tasks were identified:

- Joint inspections of manufacturers;
- Joint inspections of other economic operators (authorised representatives, importers, distributors);
- Training of inspectors;
- Management of WP 6.

[1] https://health.ec.europa.eu/document/download/ee962899-de43-42a0-ab61-caa012b16ebc_en?filename=amended_wp2022_en.pdf
[2] https://www.camd-europe.eu/joint-action-projects/jams-2-0/
[3] https://hadea.ec.europa.eu/programmes/eu4health/about_en
[4] Grant Agreement, Project summary, page 73
[5] https://www.camd-europe.eu/joint-action-projects/jams-2-0/overview-jams-2-0-work-packages/
[6] The 'Union market' refers to the territories of the European Union Member States, and due to the European Economic Area (EEA) is extended to Norway, Lichtenstein and Iceland, and via the Customs Union Agreement to Türkiye.
[7] Grant Agreement, Work Package 6 – Inspection, page 80

This is a direct continuation of the work started in the first JAMS project[8] (hereafter referred to as JAMS 1.0). In JAMS 1.0, WP 4[9] aimed at harmonising the practices of CAs with regards to the inspections of manufacturers. In JAMS 2.0, WP 6 builds upon this work to expand the scope of the joint inspections beyond manufacturers with the inclusion of authorised representatives, importers and distributors. Furthermore, it aims to put in practice the framework by actually performing joint inspections of these economic operators. WP 6 brings together participants, mainly inspectors, from 21 Member States. About 30 joint inspections were planned for manufacturers and 30 for the other economic operators.

This document constitutes a deliverable for WP 6 as listed in the Grant Agreement between participating CAs and the European Health and Digital Executive Agency (HaDEA) which is entrusted by the European Commission. The content of this deliverable represents the views of the national CAs involved as beneficiaries in JAMS 2.0 Work Package 6. They do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

[8] https://www.camd-europe.eu/joint-action-projects/market-surveillance-of-medical-devices-jams/
[9] https://www.camd-europe.eu/joint-action-projects/market-surveillance-of-medical-devices-jams/overview-of-work-packages/

II. Introduction

Market surveillance activities carried out by CAs aim to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.[10]

Inspections constitute an important part of market surveillance, allowing CAs to collect valuable data on devices that are placed on the Union market, directly at the economic operator's location, and to evaluate whether they pose a risk to public health. Therefore, as mandated in the regulations, CAs shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.[11]

As each Member State has varying levels of resources to dedicate to inspections of economic operators, as well as different areas of specialisation and focus, there is a risk of creating unfair competition between actors located in different countries, with some being more inspected than others. This lack of harmonisation could represent a threat to the good functioning of the Single Market.

The regulations require Member States to cooperate with each other and with the European Commission, and to participate, where appropriate, in international initiatives in the field of medical devices.[12] With regards to market surveillance, "*the competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States. Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation*".[13]

The JAMS 2.0 initiative is a strong European encouragement to facilitate collaboration between CAs and carry out joint market surveillance activities, such as joint inspections, as required in the abovementioned provisions. WP 6 is dedicated to the development of a consistent framework to carry out joint inspections, through the creation of templates and real on-site inspections. The economic operators in the scope of JAMS 2.0 are manufacturers (excluding custom made devices), authorised representatives, importers and distributors.

A campaign of 30 joint inspections of manufacturers (JIMs), involving more than 70 inspectors, was performed across 2024 and 2025 as part of the objectives of WP 6. In addition to the local CA, each inspection included the participation of two inspectors from

[10] MDR Art. 2 (61) / IVDR Art. 2 (64)
[11] MDR Art. 93 (3)(b) / IVDR Art. 88 (3)(b)
[12] MDR Art. 102 / IVDR Art. 97
[13] MDR Art. 93 (9) / IVDR Art. 88 (9)

different Member States, except in two instances where only one visiting inspector was available to participate. This contributed to exchange good practices, experience and expertise between inspectors, and to strengthen cooperation and harmonisation between Member States in the area of inspections of medical devices manufacturers.

The objective of this document is to provide a summary of the outcome of the campaign of JIMs performed within the framework of JAMS 2.0 WP 6. Although this report discusses frequently observed non-compliances (NC) to the regulations and makes recommendations, the primary goal of this campaign was not to conduct an exhaustive study of the medical devices manufacturing sector in Europe. Therefore, the reader should keep in mind that results may not be representative of the whole sector.

III. Abbreviations

AIMD	Active Implantable Medical Device
AIMDD	Directive 90/385/EEC relating to active implantable medical devices
CA	Competent Authority for market surveillance
CAMD	Competent Authorities for Medical Devices
CAPA	Corrective Actions Preventive Actions
DoC	Declaration of Conformity
FIR	Final Inspection Report according to MDR Article 93 (7) and IVDR Article 88 (7)
GSPR	General Safety and Performance Requirements
HaDEA	European Health and Digital Executive Agency
IFU	Instructions For Use
IMDRF	International Medical device Regulators Forum
IVD	*In vitro* Diagnostic Medical Device
IVDD	Directive 98/79/EC on *in vitro* diagnostic medical devices
IVDR	Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
JAMS 1.0	Joint Action on Market Surveillance of Medical Devices
JAMS 2.0	Joint Action on reinforced Market Surveillance of medical devices and in vitro devices 2.0
JIM	Joint Inspection of a Manufacturer
MD	Medical Device
MDCG	Medical Device Coordination Group
MDD	Directive 93/42/EEC concerning medical devices
MDITF	Medical Devices Inspectors Task Force
MDR	Regulation (EU) 2017/745 on medical devices
NC	Non-Compliance
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Surveillance
PRRC	Person Responsible for Regulatory Compliance
PSUR	Periodic Safety Update Report
QMS	Quality Management System
WP	Work Package

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V. Methodology

In the months preceding the start of the campaign of JIMs, each participating CA informed the coordinating Member State (Belgium) of the number of JIMs that they agreed to organise in their own Member State and wished to follow in other Member States. On that basis, a first planning was created to pair one host CA with two visiting CAs for each JIM. This planning was amended as needed during the campaign to ensure that the total number of inspections was maintained and that the objectives of the project were reached. In total, thirty JIMs were planned for the campaign, which started in March 2024 and ended in July 2025.

Each host CA was responsible for the organisation of the JIMs that were planned in their Member State. In order to select a suitable company to inspect, a few criteria were designed, with the main ones described below. They acted as a guideline to ensure that the JIM took place in good conditions. Ultimately, the selection of the manufacturer was the responsibility of the host CA and not all criteria needed to be met.

- The company acted as a manufacturer and placed devices on the Union market according to Regulation (EU) 2017/745 (MDR) or Regulation (EU) 2017/746 (IVDR) for regulation devices, or according to Directive 90/385/EEC (AIMDD), Directive 93/42/EEC (MDD) or Directive 98/79/EC (IVDD) for legacy devices.
- The manufacturer was likely to have its documentation in English and staff able to be inspected in this language. In case it was not possible, a budget for translation and/or interpretation was available.
- The manufacturer was likely to have the capacity to accommodate a team of at least three inspectors (one from the host CA and two visiting inspectors).
- The manufacturer had at least some of its production process occurring on-site.
- The manufacturer needed to be inspected in the near future.

Once a suitable manufacturer was found, the host CA acted as the contact point between the inspection team and the company. This included regular inspection planning and preparation, such as announcing the inspection, deciding inspection dates, asking for documents to be reviewed prior to the inspection, and communicating the agenda.

A lead inspector was chosen among the JIM team, often from the host CA but not necessarily. In cases where the lead inspector was from a visiting CA, the host CA was still tasked with handling the communication with the company.

JIMs took place over two to three days at the manufacturer's premises. The scope of the inspection was decided by the JIM team and would normally cover the following topics:

- Premises where production or storage activities took place;
- Quality management system (QMS) of the company;

- Technical documentation of selected devices.

The legal requirements used as a basis for the JIM were MDR or IVDR, along with, as applicable, MDD, AIMDD or IVDD (for legacy devices), and national legislation. Relevant standards and guidance documents were also used as a reference if applicable.

At the end of the inspection, the preliminary list of non-compliances (NC) was communicated to the company. The grading of NCs was harmonised according to the following definitions (Table 1):

Table 1: Definitions used during this JIM campaign for grading non-compliances and observations.

Definitions of non-compliances and gradation	
Critical non-compliance	A deficiency which has produced, or leads to a significant risk of producing, a product which may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of public health, and may require immediate action.
Major non-compliance	Not a critical non-compliance but a deficiency which indicates a significant deviation from requirements laid down in the medical devices legislation. A major non-compliance could also be a combination of several minor non-compliances, none of which on their own may be major, but which may together represent a major non-compliance and should be explained and reported as such.
Minor non-compliance	Minor deficiency which cannot be classified as either critical or major non-compliance, but is a deviation from requirements laid down in the medical devices legislation.
Observation	Is not a non-compliance against the medical devices legislation but may be a finding or statement to prompt the company to improve future practice, performance or procedures.

After the JIM, an inspection report was sent to the manufacturer that included the final list of the findings. The next steps varied depending on the national legislation of every Member State. In most cases, the company was asked to establish a plan of corrective actions and preventive actions (CAPA) to provide corrections and corrective actions for any NC that was identified within a reasonable amount of time. The host CA will be responsible of the follow-up of the CAPA plan, based on their own practices and the severity of the NCs.

After the JIM was concluded, each host CA was asked to fill a 'joint inspection reporting form' with the following information:

- Data on the inspected manufacturer;
- Types and classes of inspected devices;
- Number, grading and description of the NCs;

- Actions taken following the inspection, if applicable.

This data was collected by the coordinating Member State. Results were compiled and analysed in Microsoft Excel. NCs were assigned to different categories based on the topics that were found non-compliant. This allowed to draw conclusions on the most frequently observed NCs, highlighting possible trends.

The summary report was drafted by the coordinating Member State and submitted to all participating CAs for revision. As a deliverable for WP 6, it was also submitted to HaDEA and shared with all WP leaders of JAMS 2.0. This report is public and may be published on the CAs' websites and disseminated by any other means.

VI. Overview of the inspected manufacturers

i. Geographical distribution

Twenty-one Member States took part in JAMS 2.0 WP 6. Of these, fourteen CAs organised at least one JIM in their country. The list of countries where manufacturers were located is provided in Figure 1.

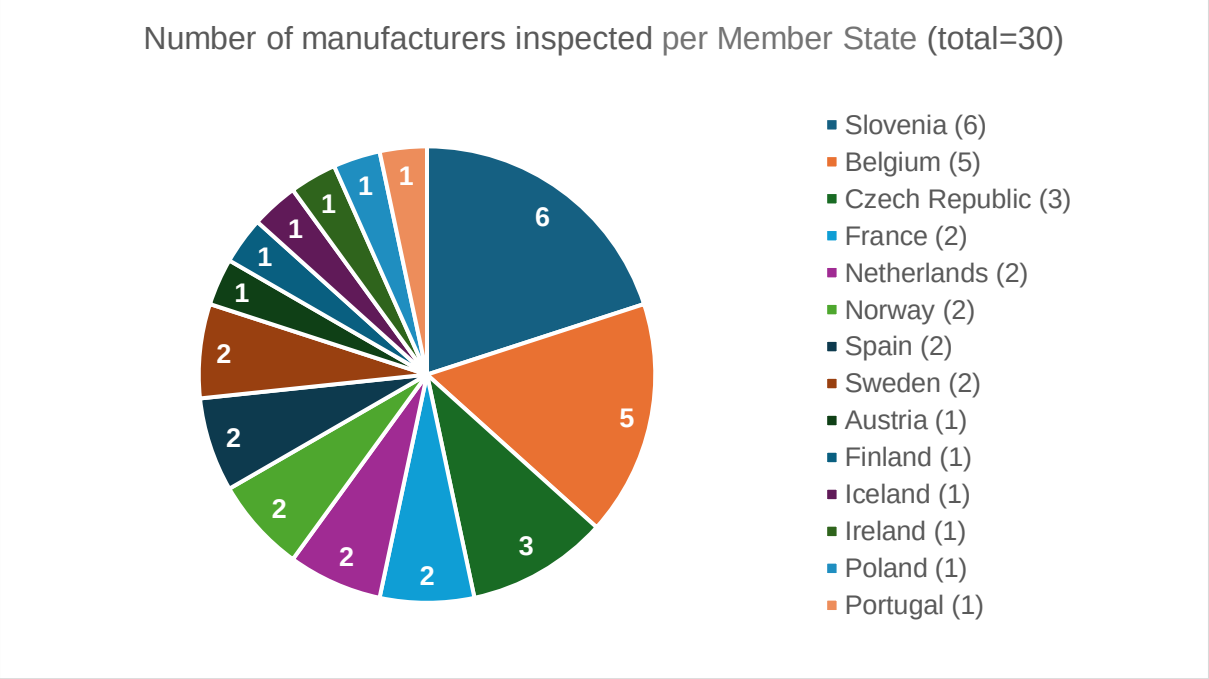

Figure 1: Number of manufacturers inspected in each Member State.

The CAs that organised the most JIMs were Slovenia (6), Belgium (5) and the Czech Republic (3). Together, these three countries account for almost half of the inspected manufacturers (14 JIMs out of 30, 47%). Then, France, the Netherlands, Norway, Spain and Sweden each organised two JIMs, and Austria, Finland, Iceland, Ireland, Poland and Portugal organised one each.

ii. Categories of enterprises

Data about the approximate number of employees and annual turnover of each manufacturer was collected, when available. This allowed to categorise the companies into 'micro', 'small', 'medium', or 'large' enterprises, according to the criteria established in Commission Recommendation 2003/361/EC concerning the definition of SMEs.[14]

As presented on Figure 2A, no micro enterprises were included in this campaign. There were 6 small (20%), 13 medium (43%) and 11 large (37%) enterprises. This means that

[14] Commission Recommendation (2003/361/EC) of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises

large companies were probably overrepresented compared to the actual sector. According to MedTech Europe, the medical devices sector in Europe consists of 90% of SMEs (micro, small and medium enterprises).[15] This overrepresentation could be a by-product of the selection criteria applied to screen for suitable manufacturers. Indeed, manufacturers able to accommodate a large inspection team, with documentation in English as well as on-site production would likely be larger companies.

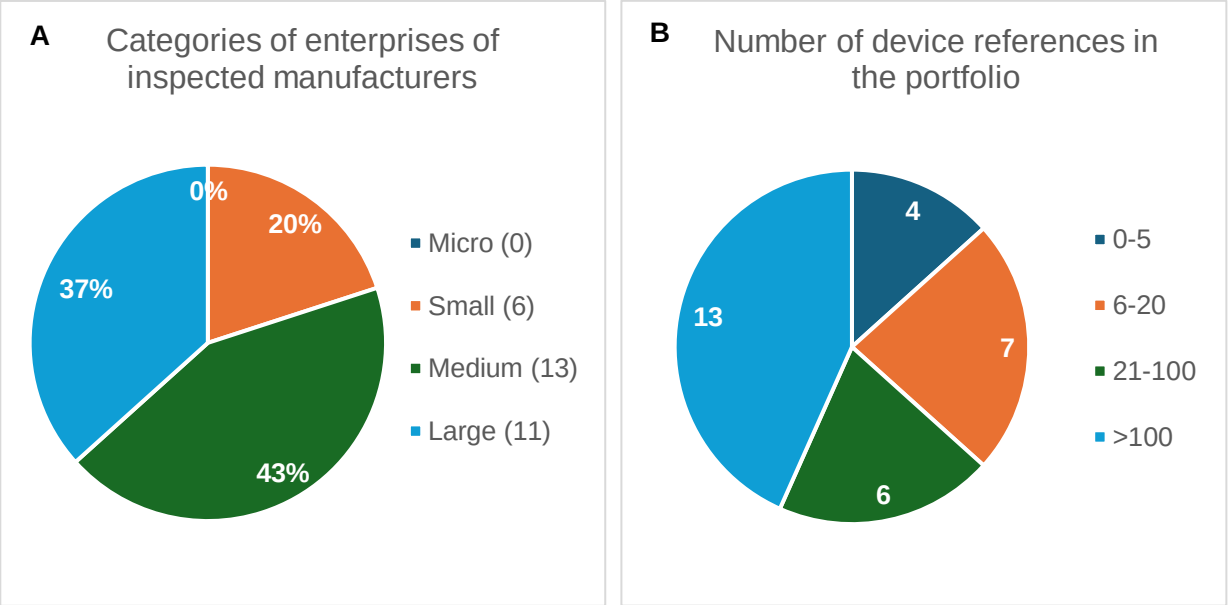

*Figure 2: (**A**) Proportion of inspected manufacturers in each size category of enterprise (micro, small, medium or large enterprise) according to their number of full-time employees and their revenue. (**B**) Number of manufacturers marketing 5 devices or less, between 6 and 20 devices, between 21 and 100 devices, or more than 100 devices.*

The number of devices (individual references) manufactured by each company was also collected and divided into four categories: 5 devices or less, 6 to 20 devices, 21 to 100 devices, and more than 100 devices. Figure 2B shows the proportions between these categories.

We can see that most manufacturers (13 companies, 43%) marketed more than 100 different devices. Seven companies (23%) marketed between 6 and 20 devices, six (20%) had a portfolio of 21-100 devices and finally only four (13%) manufacturers had 5 devices or less.

The relationship between the category of enterprise (i.e. size of the company) and the number of devices marketed is shown on Figure 3. Small manufacturers mainly marketed between 6 and 100 devices, with one marketing more than 100. There was a larger proportion of medium and large manufacturers with a portfolio of more than 100 devices

[15] MedTech Europe, Facts & Figures 2025

(46% and 54% respectively), but some of them also had 5 devices or less, a category that was not represented in small manufacturers.

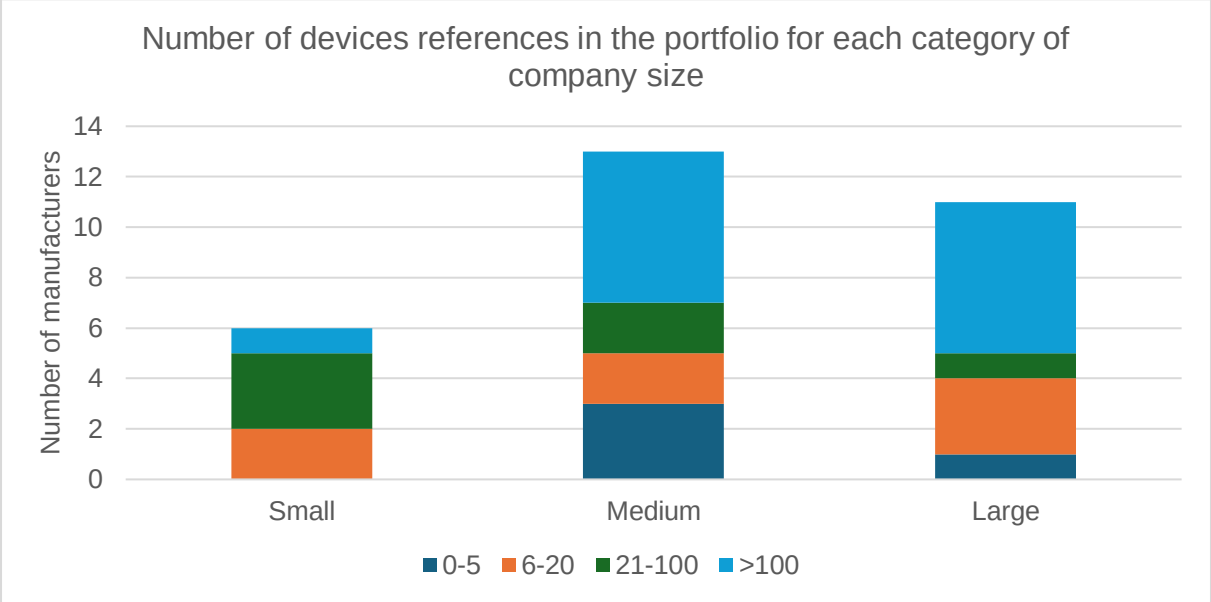

Figure 3: Number of devices marketed by manufacturers, depending on whether they are small, medium or large enterprises.

iii. Types of devices manufactured

The JAMS 2.0 joint action was applicable to both medical device (MD) and *in vitro* diagnostic medical device (IVD) companies. However, in the selection of manufacturers to inspect, CAs overwhelmingly chose MD manufacturers, as shown on Figure 4.

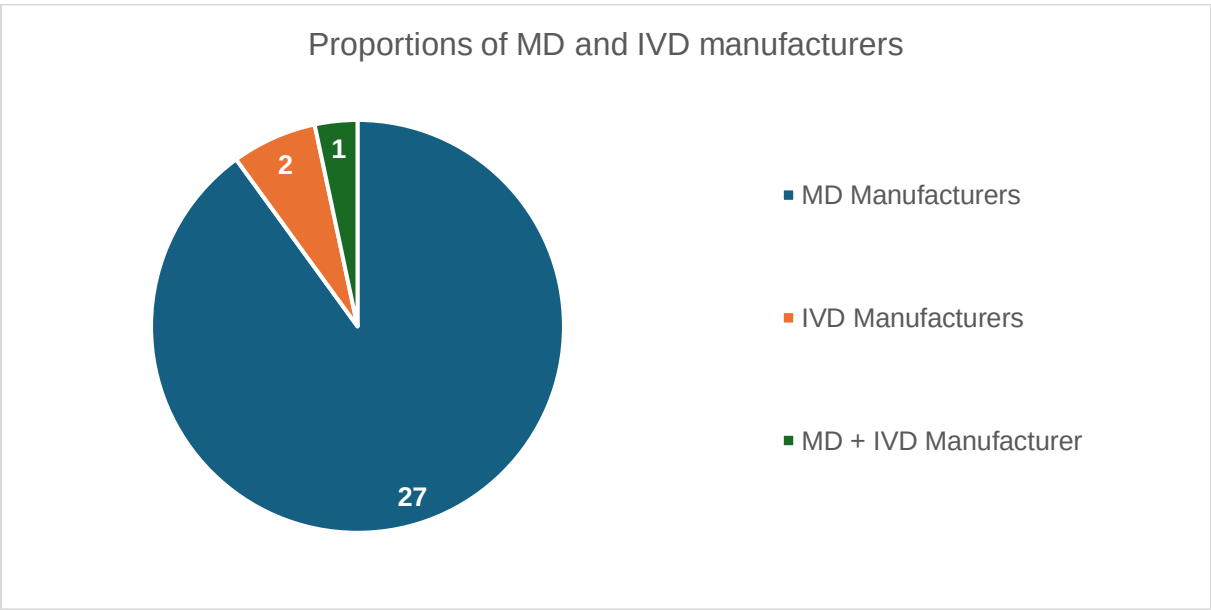

Figure 4: Proportions of manufacturers that produced medical devices (MD), in vitro medical devices (IVD) or both.

Indeed, only 2 companies manufactured IVDs, 27 manufactured MDs, and 1 manufactured both. The IVD sector is therefore only represented by three manufacturers (10%) in this campaign.

When it comes to classes of devices, they were all represented to some degree for MDs, as shown on Figures 5 and 6.

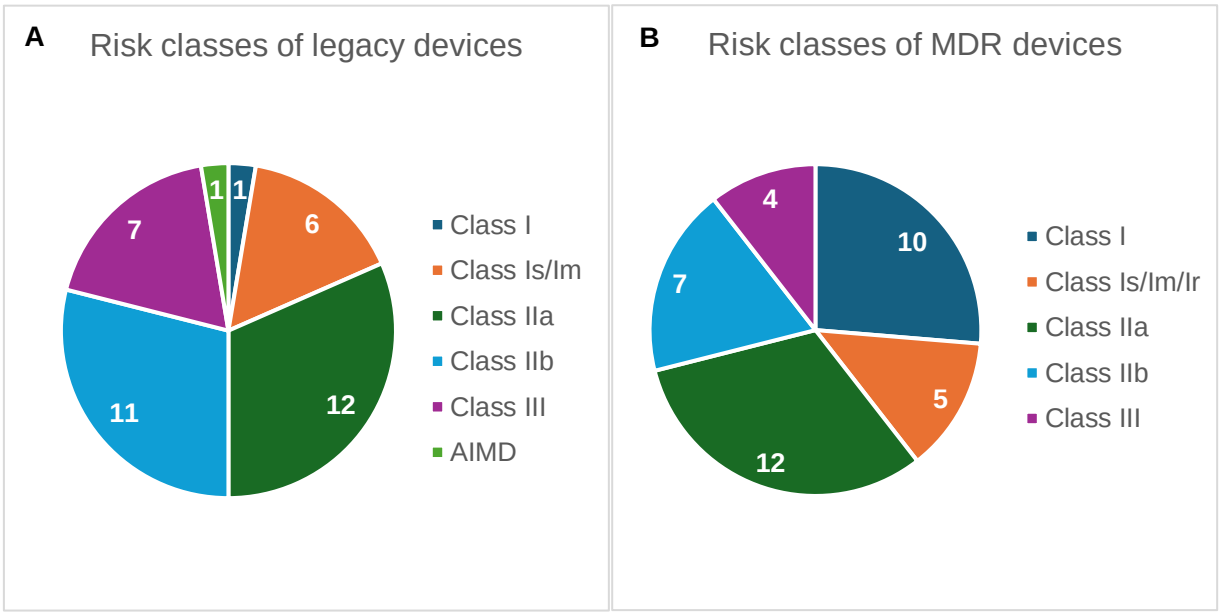

*Figure 5: Numbers of manufacturers placing each risk class of devices on the market (**A**) according to Directive 93/42/EEC or Directive 90/385/EEC (legacy devices) or (**B**) according to Regulation 2017/745 (MDR devices).*

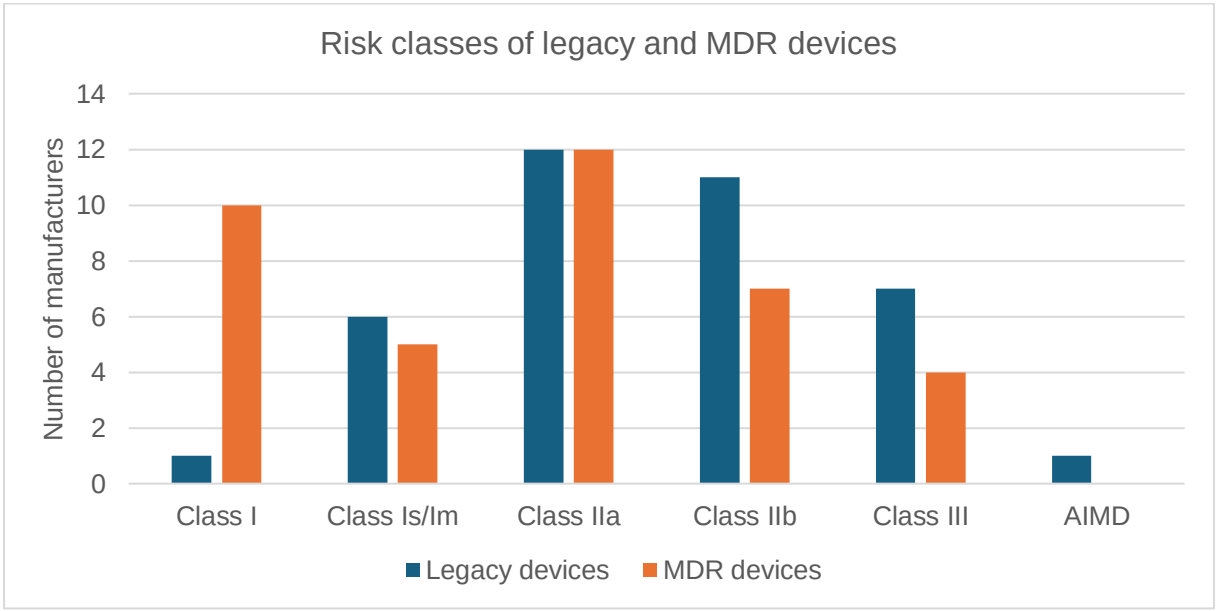

Figure 6: Numbers of manufacturers placing each risk class of devices on the market according to Directive 93/42/EEC or Directive 90/385/EEC (legacy devices) or according to Regulation 2017/745 (MDR devices).

Figures 5 and 6 show that all risk classes of devices were represented in this campaign, both as legacy devices and as MDR devices. Unsurprisingly, class I devices were almost all placed on the market following the MDR, as they do not benefit from the transition period. The only exception is in the case of up-classified devices (i.e. devices which are class I under MDD but belong to a higher class under MDR), which explains the occurrence of one class I MDD device. As for other classes, class IIa devices were the most common, followed by class IIb, class III and then class Im, Is and Ir devices. One active implantable medical device (AIMD) was also present as a legacy device.

Classes Is/Im/Ir and IIa devices were placed on the market as MDR devices almost as frequently as they were as legacy devices. On the other hand, classes IIb and III were still found more frequently as legacy devices. This could be due to sampling, but might also be an indication that while the transition to MDR is well under way, higher classes may take more time to get certified due to their complexity and because of more stringent conformity assessment procedures.

Medium and large companies manufactured all risk classes of devices, including class III and AIMD (Figure 7). In contrast, small manufacturers in our sample did not manufacture class Is/Im/Ir or class III devices. Therefore, it is possible that the overrepresentation of larger companies in our sample may also have led to an overrepresentation of these risk classes of devices.

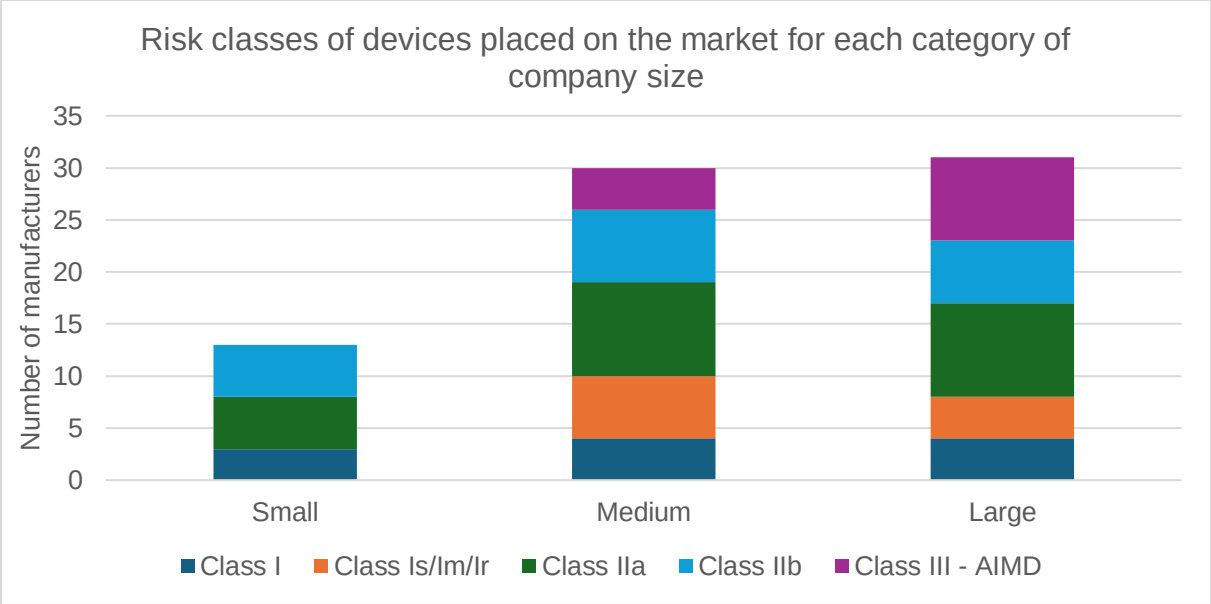

Figure 7: Risk classes of devices marketed by manufacturers, depending on whether they are small, medium or large enterprises.

A wide range of medical device types was represented among the inspected manufacturers. They included, in no particular order:

- Surgical sutures, meshes and needles;
- Aerosol inhalation monitors, peak flow meters, spirometers, ECG devices, pulmonary function test devices;
- Dental implants and dental prosthetic components, instruments dedicated to dental implants;
- Devices for oral care of patients in intensive care;
- Devices for contact lenses care, ophthalmic solutions;
- Wound dressings;
- Infusion sets;
- Electric suction devices;
- Hospital beds, stretchers, chairs and mattresses;
- Cell culture media used in assisted reproductive technologies;
- Medical gas devices, equipment for medical gas systems, bedhead units, oxygen therapy devices, medical suction units, and medical support equipment;
- Syringes, catheters, wires, stents, needles;
- Devices for premature infants in neonatal care units such as feeding bottles, enteral bottles, breast milk collection sets;
- Hearing aids, implants;
- Magneto therapy devices and ultrasound devices;
- Laser systems and articulated arms, laser consoles, laser probes and associated consumables;
- Gynaecological, respiratory, gastroenterology and urology devices;
- Enteral feeding sets;
- Resins for 3D printed dental devices and surgical guides;
- Extracorporeal immunoadsorption devices;
- Imaging and PACS software;
- High-frequency ultrasound imaging systems and probes;
- Ultrasound probes, scanners and software.

Due to the limited number of IVD manufacturers included in this campaign, the range of IVD types was relatively narrow (Figure 8).

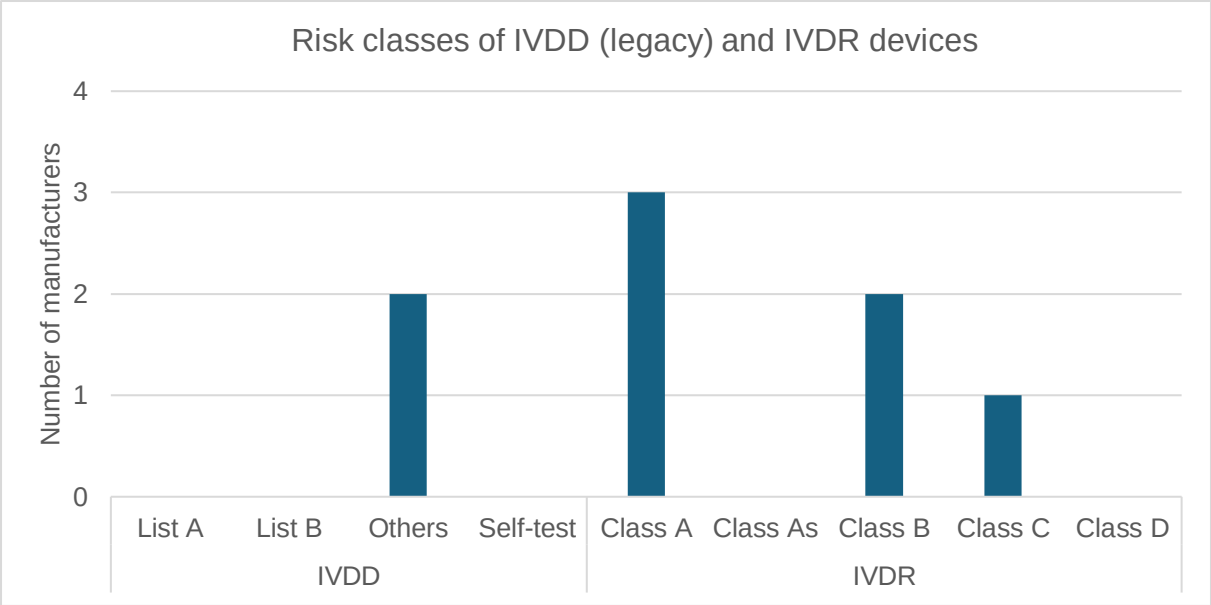

Figure 8: Numbers of manufacturers placing each risk class of IVDs on the market according to Directive 98/79/EC (IVDD - legacy IVDs) or according to Regulation 2017/746 (IVDR devices).

Both legacy IVDs were in the 'Other' category, i.e. not listed in List A or List B of IVDD, nor a self-test. Three IVDs were in class A according to IVDR, two in class B and one in class C.

The inspected IVDs covered a range of diagnostic applications, such as clinical diagnostics, microbiology, immunodiagnostics, cancer testing, infertility testing, along with the reagents and consumables needed for these applications.

iv. Conclusion on the inspected manufacturers

The manufacturers selected for this joint inspection campaign represented a diverse group, though there was a noticeable bias toward larger companies with extensive device portfolios. The MDs manufactured were very diverse, again probably with a bias towards higher classes of devices. The share of IVD manufacturers in our sample was small with only 3 companies, including one that produces both MDs and IVDs. It is also worth noting that nearly half of all manufacturers were located in only three countries.

In conclusion, this sample should not be considered representative of the whole MD/IVD manufacturing sector in the European Union. Therefore, attention should be taken not to draw wide-ranging conclusions from this report. Its goal was first and foremost to test the framework to conduct joint inspections of manufacturers and to harmonise inspection activities throughout Europe, not to conduct an exhaustive study of the sector.

VII. Results

i. General overview

In the process of conducting these 30 JIMs, 366 findings were observed, including 217 non-compliances:

- 0 critical NC (average of 0/JIM)
- 45 major NC (average of 1.5/JIM)
- 172 minor NC (average of 5.7/JIM)
- 150 observations (average of 5.0/JIM)

It should be noted that inspections are always based on sampling, and it is not possible to cover the entire scope of MDR or IVDR and national legislation during a single inspection.

The absence of a critical NC is to be pointed out, as no NC was considered serious enough to constitute an unacceptable risk to public health. Therefore, no immediate actions (e.g. placing devices in quarantine or seizing them, organising a withdrawal or a recall of devices placed on the market) needed to be taken.

Regarding the other findings, there were on average 1.5 major NC, 5.7 minor NC and 5.0 observations per inspection. However, there was an important variability from one JIM to the other, as seen on Figure 9.

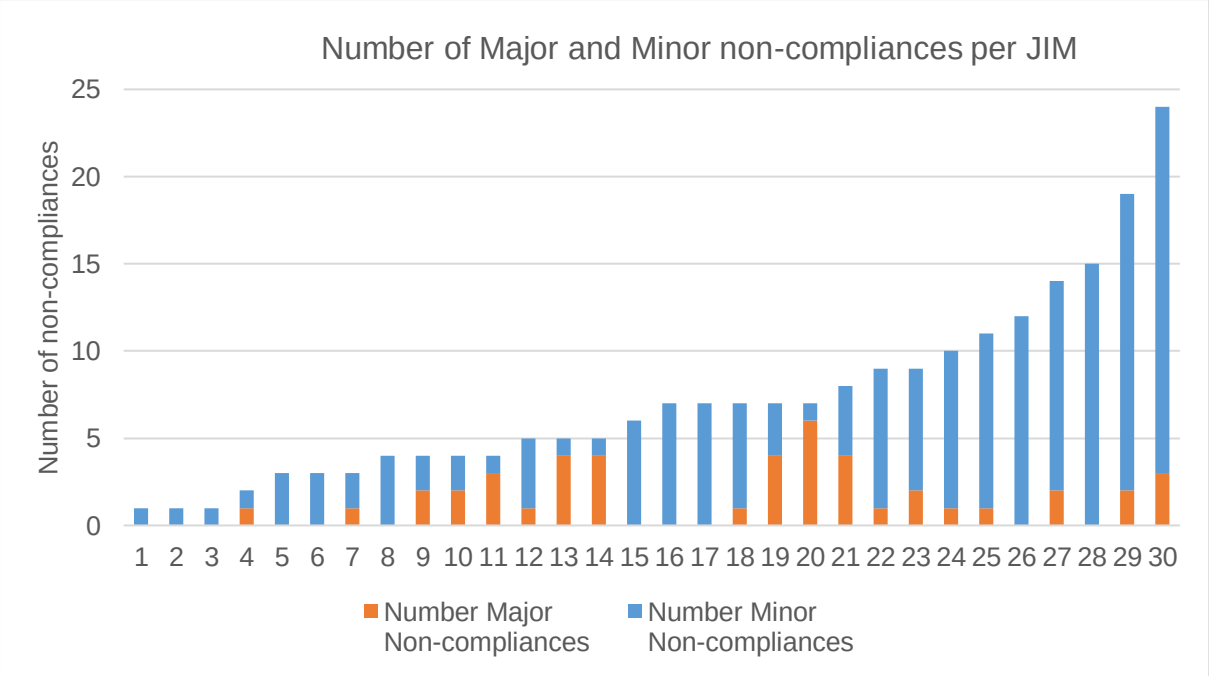

Figure 9: Number of non-compliances observed in each JIM. Minor NCs are in blue and Major NCs are in orange. The JIMs are sorted by total number of NCs.

The three most compliant companies only got one minor NC, while on the other end of the spectrum, a manufacturer received twenty-four NCs, including three major ones. In some

instances, all or most NCs were minor, while in other JIMs a larger proportion of NCs were considered major.

This important variability can be attributed to two factors. First, some manufacturers are simply more compliant than others, leading to fewer NCs identified. Second, practices in the assignment of NCs differ from one Member State (or even inspector) to the other. In some cases, inspectors tended to list all deficiencies separately, resulting in a large number of them, while in other cases they were grouped together by topic, sometimes resulting in the upgrade of several minor NCs to one major NC.

For this reason, while the total number of NCs will still be referenced in the following analysis, attention will be focused on the number of JIMs for which a topic was found non-compliant. Example: in *JIM A* there are three different NCs on the management of documents and records, while in *JIM B* the three same NCs are grouped together as a major NC. To avoid placing more emphasis on *JIM A* (number of NCs) or on *JIM B* (gradation of NCs) despite the fact that the shortcomings were exactly the same, we would simply state that in both cases the management of documents and records was found non-compliant.

To account for this, the different topics that are part of an inspection were grouped in seventeen different categories (see section ii below for the full list). Whenever a process or a document was found non-compliant, the category that covers it was considered non-compliant, irrespective of the number of NCs or their grading. A single NC could lead to multiple categories being found non-compliant if the NC was broad, and inversely a single category could be linked to multiple NCs. This process helped classify NCs and reduce the bias due to the way inspectors would group and grade NCs.

Figure 10 shows the number of categories found non-compliant per JIM. Three manufacturers had only one category that was non-compliant, while another had twelve (out of a total of seventeen different categories). Because of this repartition per category, the differences observed between JIMs should be more attributable to manufacturers' compliance and less to bias in how NCs are attributed. Of course, the bias can never be totally eliminated as JIMs may have varied in duration and scope, JIM teams varied in experience, expertise and focus, which would be reflected in the outcome of the inspection.

Although one of the main objectives of the campaign was to test and implement the joint inspection framework, placing greater emphasis on assessing manufacturer conformity, standardising inspection practices and training would enhance the reliability and comparability of future inspection outcomes, notably by providing training to inspectors (e.g. the training session to be organised as part of JAMS 2.0 WP6).

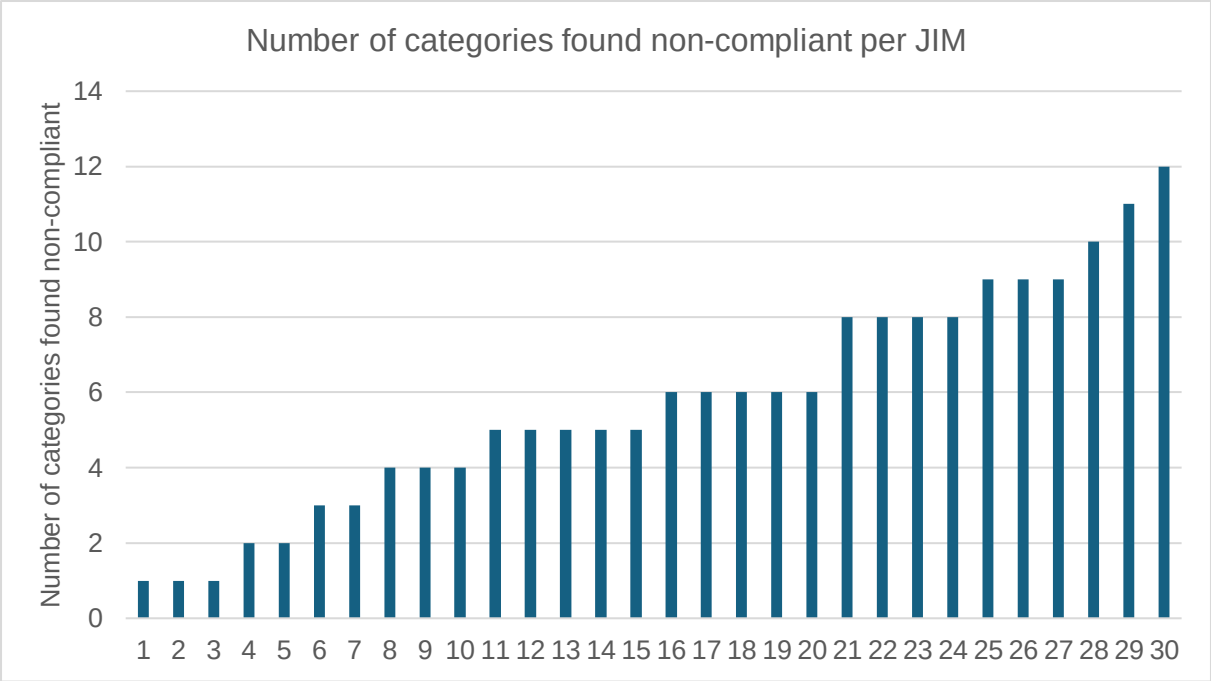

Figure 10: All NCs were sorted into 17 categories grouping most topics that are usually part of a manufacturer's inspection. For each JIM, the number of categories found non-compliant is shown in this figure, sorted by the number of non-compliant categories.

Based on these results, we tried to determine if manufacturer compliance could be correlated to other factors. Companies that were inspected corresponded to small, medium and large enterprises. A slight correlation with the number of non-compliant categories could be observed (Figure 11), larger companies being overall more compliant, although it was not a statistically significant difference in the test that was run (Kruskal-Wallis test, p-value = 0.053).

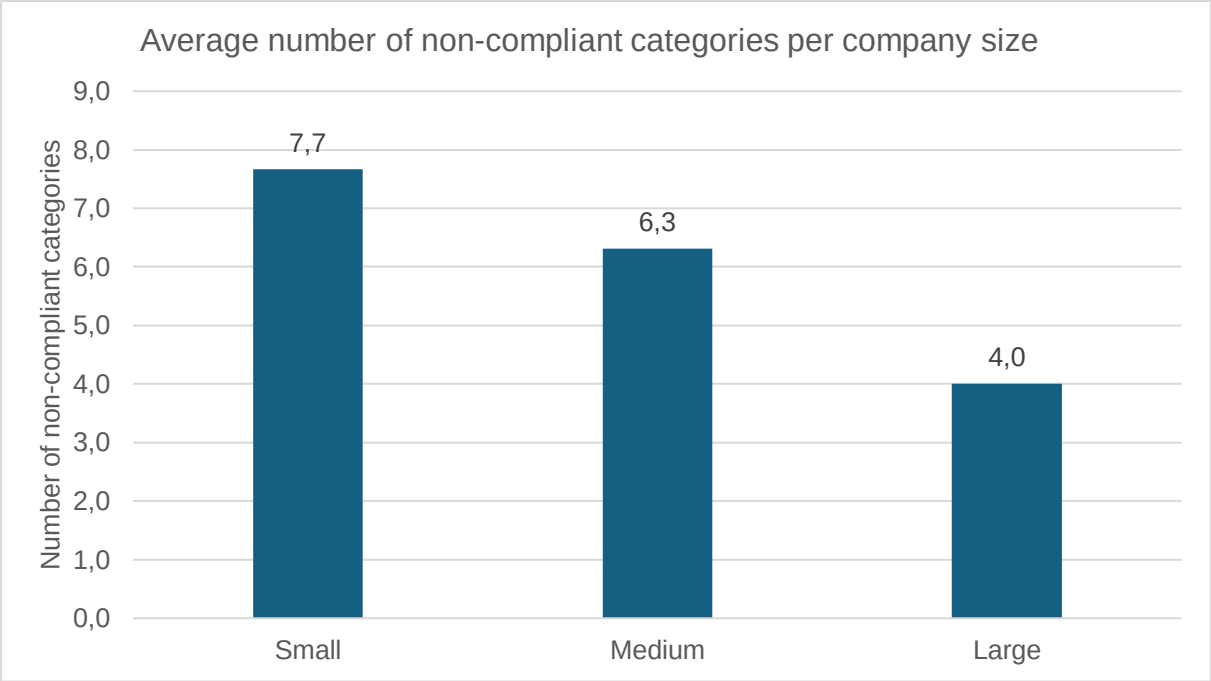

Figure 11: Average number of non-compliant categories for each company size (small, medium or large). Considering the low number of inspected companies, the differences that are seen on this figure are statistically non-significant (p=0.053).

Other tested correlations included the number of devices in the portfolio, as well as companies being in the MD or IVD sector, but none showed any correlation (Table 2).

Table 2: Correlation between three different factors (company size, portfolio size and sector) and the average number of NC categories. The statistical analysis was performed with Kruskal-Wallis and Mann Whitney tests. The p-value is shown for each test. n.s.= non-significant.

Trends between types of manufacturers	
Company Size	Average NC categories
Small	7,7
Medium	6,3
Large	4,0
p-value	0,053 (n.s.)
Portofolio Size	Average NC categories
0-5	6,3
6-20	5,9
21-100	4,3
>100	6,2
p-value	0,552 (n.s.)
Sector	Average NC categories
MD	5,6
IVD	6,3
p-value	0,7878 (n.s.)

Considering the small sample size, statistically significant differences were unlikely to begin with. However, this trend regarding the size of the companies, although statistically non-significant, aligns with anecdotal experience observed on the field. Larger companies often have more resources to dedicate to regulatory compliance and quality assurance, resulting in a more robust QMS and fewer deficiencies. This remains to be confirmed with more data.

ii. Topics of non-compliances

Inspections of medical devices manufacturers can cover many different topics, each of which could potentially lead to a NC. In order to analyse the results more efficiently, inspected areas were grouped within categories based on the MDR/IVDR requirements and on the ISO 13485 standard. Then each NC was linked to at least one category, sometimes more if the NC touched on different topics.

The different categories are:

- Conformity assessment – Qualification & Classification – Declaration of conformity;
- Registration requirements – Eudamed – Application of the UDI system;
- Marketing information – Website – Distance sales;
- Facilities: Production and Storage areas;
- Quality Management System (following ISO 13485 chapters):
    - General requirements of the QMS: Management of documents & records, Strategy for regulatory compliance, Change control;
    - Management responsibility;
    - Resources management: Human resources, Infrastructures, Equipment, Work environment;
    - Product realisation: Management of suppliers & subcontractors, Manufacturing processes, Quality control, Release, Traceability;
    - Measurement, Analysis & Improvement: Management of complaints, CAPA, Internal audits, Vigilance system;
- Technical file (following MDR/IVDR Annexes II & III):
    - Description and Specification;
    - Label and Instructions for use (IFU);
    - Conception and Manufacturing;
    - General Safety and Performance Requirements (GSPR);
    - Benefit-Risk analysis and Risk management;
    - Verification and Validation: Clinical evaluation, Biocompatibility, Stability, Validations;
    - Post-Market Surveillance (PMS): PMS/PMCF plan, PMS/PMCF report, PSUR.

Results will be presented in more details for all categories where non-compliances were identified in at least ten different JIMs (a third of all inspections). For each of them, the most frequently observed NCs will be summarised.

1. General requirements of the QMS

The category with the most NCs identified was the QMS – General requirements, corresponding to Chapter 4 of ISO 13485. This category included the management of documents and records, strategy for regulatory compliance and change control. Non-compliances on these topics were found in 19 JIMs (63%), accounting for a total of 43 NCs.

A lot of NCs were observed on the management of documents and records. In many cases, it was instances of forms or documents incorrectly filled, missing information or not following good documentation practices. Other issues were :

- Using non-controlled versions of documents;
- Insufficient retention time of documents;
- Lacking security of documents, including the back-up strategy of electronic documents.

In the management of changes, the main source of NCs was a lack of details in the change control procedure. Frequent issues were:

- Insufficient details on how to determine if a planned change would be substantial, significant or minor;
- Insufficient details on when and how to notify a change to the notified body.

When it comes to the strategy for regulatory compliance, frequent issues were:

- Missing national legislation;
- Using outdated versions of the standards;
- Lack of description of the conformity assessment requirements.

Finally, a couple of NCs were observed because of a lack of periodic review of the QMS by the company.

2. Label and IFU

The second category that was found the least compliant was the label and IFU. Non-compliances on these topics were found in 19 JIMs out of 30 (63%), accounting for a total of 25 NCs.

One important issue that affected both the label and the IFU was related to the application of languages requirements. For instance, some manufacturers didn't have the labelling information or the IFU in all the languages required by the Member States where the devices were made available. In other cases, this requirement was not covered by the QMS to ensure compliance to national languages requirements.

Other frequent issues related the IFU were:

- Missing information;
- Lack of clarity;
- Warnings not aligned with the risk analysis and the clinical evaluation report;
- Intended population not clearly defined.

Other frequent issues related to the label were:

- Missing information;
- Missing harmonised symbols;
- Label readability;
- Incorrect NB number associated with the CE marking.

3. Product realisation

The third least compliant topic was the QMS – Product realisation, corresponding to Chapter 7 of ISO 13485. This category included the management of suppliers & subcontractors, manufacturing processes, quality control, batch records, release and traceability. Non-compliances on these topics were found in 17 JIMs (57%), accounting for a total of 38 NCs.

A common issue was an insufficient level of control of the suppliers and subcontractors of the company. Frequent findings were:

- Procedure not detailed enough;
- Quality agreement missing key elements, such as the notification of supplied product changes to the manufacturer;
- Incomplete list of suppliers and subcontractors;
- A lack of audits of critical suppliers and subcontractors, or a lack of follow-up after these audits.

Regarding the manufacturing process, findings were varied considering the diversity of devices and production processes. Some examples of issues were:

- Insufficient control of contamination in the warehouse;
- Lack of or unreadable identification of materials and products in storage;
- Insufficient information on the production steps;
- Lack of or insufficient line clearance between work orders;

- Issues with gowning, such as inadequate supplies and lack of information on the gowning requirements;
- Issues with the method of sampling of products or materials to be tested in quality control;
- No guarantee on the independence between operators working in production and quality control.

Finally, issues were found in the traceability of products from materials to devices to customers, and inversely.

4. PMS system

The next category was the PMS system. Non-compliances on these topics were found in 16 JIMs (53%), accounting for a total of 19 NCs.

The most frequent deficiencies observed on this topic were that the PMS system was not covering all requirements from Annex III of the regulations. Missing elements included:

- No systematic and proactive process to gather the data;
- No literature review;
- No collection of information from other devices;
- No indicators or thresholds defined.

In too many instances, there was simply no PMS plan or report. Or a report existed from a few years ago but was not kept up to date.

Some other issues were:

- Timelines to conduct PMS activities not described in a procedure, or activities not performed according to the defined timelines;
- Collection of data from only the national market and not others;
- Issues related to the PSUR (no estimation of the population size, no impact analysis of CAPA, grouping devices without justification).

5. Risk management

Technical File – Benefit-risk analysis and risk management was the next category with the most observed NCs. It was found non-compliant in 16 JIMs (53%), accounting for 17 NCs.

By far the most frequent source of NC was the risk analysis not considering some risks that were relevant to the device. These potential risks may have been found in the clinical evaluation report, the literature analysis, the IFU warnings and precautions, or from the

inspector's professional experience, but were absent from the risk analysis. This means that there was no proof that they had been mitigated and brought to an acceptable level.

Some other issues were:

- Risk analysis not carried out according to ISO 14971 despite the documentation stating that it was;
- Inconsistencies in the hazard matrix between different documents;
- Risk control measures not considered sufficient, verification of risk control measures not documented;
- Risk management not kept up to date, risk management report not updated recently.

6. Measurement, Analysis & Improvement

The next category was QMS – Measurement, Analysis & Improvement. This included the management of complaints, NCs, CAPAs, internal audits and the reporting obligations under the vigilance system. Non-compliances on these topics were found in 14 JIMs (47%), accounting for a total of 32 NCs.

With regards to the vigilance system, the main issues identified were shortcomings in the procedures to report these various vigilance events, for instance:

- Lack of clarity, process not maintained effectively;
- Insufficient process to detect significant trends and to report them;
- Absence of guarantee that a reportable event will be notified to the CA within the required timelines.

The company actually failed to report a serious incident to the CA in one case, and to report a safety corrective action in another.

In the CAPA process, some issues were:

- Insufficient verification of CAPA effectiveness;
- Process does not ensure that the root cause of a NC is found;
- Procedure does not sufficiently detail the process.

Internal audits:

- Competence and training of auditors not sufficiently documented;
- Procedure does not guarantee that internal auditors don't audit their own work;
- Reports not written in the defined timeline;
- Lack of clarity as to what clauses were covered by the audit plan and reviewed during the audit.

Issues relating to complaints management were all linked to insufficiently detailed procedures, e.g.:

- Procedure does not set fixed timelines to evaluate if a complaint is a serious incident that should be notified to CAs;
- Procedure does not sufficiently describe how to treat a complaint that corresponds to a serious incident;
- Procedure does not provide a link between complaints and NCs;
- Procedure does not describe how to fill essential information in the complaints form.
- Information in the form is not detailed enough to allow for trending.

Finally, regarding NCs, the main point was a lack of a procedure (or insufficiently detailed procedure) for monitoring and handling NCs.

7. Management of resources

The next category was QMS – Management of resources. Non-compliances on these topics were found in 14 JIMs (47%), accounting for a total of 23 NCs.

A large proportion of NCs related to human resources, and more specifically to the PRRC requirements introduced in the MDR and the IVDR. The issues were varied, including:

- Job description not mentioning all the PRRC responsibilities as defined in art 15 (3);
- PRRC not registered in Eudamed, or with mismatches in the list of responsibilities;
- PRRC signing the DoC without a document officially giving him authority to do so;
- No evidence of qualification according to art 15 (1);
- PRRC not in the organisation despite the company not being a micro or small enterprise;
- Job description not mentioning the training needs for the PRRC.

Other deficiencies related to human resources included:

- Trainings not recorded/documented;
- Training plan not specific enough, no annual training plan;
- Job descriptions not up to date;
- Competences needed for employees not specified.

When it came to equipment, the observed issues were:

- Inadequate maintenance of production equipment;
- No continuous temperature control and no mapping of temperatures of fridges and freezers;
- Measuring equipment not sufficiently monitored, validation overdue;
- Mistake in identification of equipment;

- Instructions of use of a production equipment only available in English, which was not understood by all operators.

Finally, two issues were seen with regards to infrastructure:

- No temperature monitoring in the final product storage room;
- Cleaning procedures in the warehouse not sufficiently defined in a procedure.

8. Verification and Validation

The next category was Technical File – Verification and Validation. This included clinical evaluation, biocompatibility, stability and product validation. Non-compliances on these topics were found in 13 JIMs (43%), accounting for a total of 16 NCs.

Deficiencies related to the clinical and biological (biocompatibility) evaluation were the most common:

- No clinical evaluation plan, report or procedures;
- Clinical or biological evaluation not kept up to date;
- Equivalence to other devices insufficiently demonstrated;
- Shortcomings in the biocompatibility analysis (duration of use of the device, information on raw materials, types of tests performed);
- Conclusions of the literature search not presented in the clinical evaluation report;
- Exclusion of tests insufficiently justified.

Other issues related in this category were:

- No usability study;
- Not enough evidence that the environmental conditions during storage and transport will not negatively impact the device or its packaging;
- Shortcomings in the validation of a process (e.g. sterilisation).

9. Conformity assessment – Qualification & Classification – Declaration of conformity

This category includes different topics that are related to conformity assessment of a device, including the determination of its status as a medical device and its risk class, the conformity assessment process, and the establishment of the declaration of conformity (DoC) and the addition of the CE mark to the device. Non-compliances on these topics were found in 11 JIMs (37%), accounting for a total of 15 NCs.

The most frequent NC in this category is caused by mistakes made in the DoC, in large part due to the intended purpose of the device missing from the document or not

corresponding to the one stated in other documents. Other points from Annex IV of the regulations were sometimes also missing.

Other issues included:

- Procedures for establishing the DoC not fully implemented or not followed;
- DoC signed by unauthorised personnel;
- Device placed on the market without having followed a conformity assessment;
- CE mark not appearing directly on the devices, or not compliant with regulatory requirements;
- Scope on certificates not covering the actual area of application.

On the other hand, some categories were found much more compliant, leading to few NCs (Table 3).

Table 3: Categories of topics found most compliant during this JIM campaign. For each category, the number of total NCs is indicated, as well as the number of JIMs where this topic was found non-compliant.

Category	**# NCs**	**# JIMs**
QMS – Management responsibility	1	1
Technical file – Conception and manufacturing	1	1
Marketing information – Website – Distance sales	2	2
Registration requirements – Eudamed – UDI system	4	4
Technical file – GSPR	5	4

In addition to NCs, JIM teams often formulated observations, i.e. findings that did not constitute a NC but opportunities for the company to improve their practices, sometimes as a preventive action before the situation escalades into a NC.

In many cases, the topics covered by observations were very similar to those of NCs. Some of the main sources of observations were also strongly represented in the list of NCs:

- Management of documents and records;
- Management of suppliers;
- Training;
- Manufacturing;
- Verification and validation;
- PMS;
- Risk management.

On the other hand, a couple of other topics appeared more frequently in observations than in NCs. One example was the need to have a back-up for the functions of PRRC or Quality Assurance manager, something that is not explicitly required in the regulations but that is important to ensure the continuity of these important roles. Another one was about registration obligations. Indeed, as the use of EUDAMED was not mandatory yet, these issues were typically classified as observations.

iii. Follow-up after the inspections

After the JIM was performed, each company received an inspection report summarising the findings and listing the NCs. In most cases, the manufacturer was requested to submit a CAPA plan to correct all NCs. This CAPA plan consisted of:

- Finding out the root cause of the NC;
- Correction of the NC;
- Corrective action to eliminate the root cause;
- Preventive action to eliminate or prevent other potential linked NCs;
- Verification of the implementation and of the effectiveness of these actions;
- Implementation dates of these actions.

If the JIM team did not agree with all proposed actions, several rounds of exchange could be done until the CAPA plan was approved for all NCs.

In some Member States, practices could differ slightly. For instance, three companies received oral warnings, and three companies were given fines, in accordance with national legislation.

The implementation of the CAPA plans by the manufacturers may be checked by their local CA on a timeline depending on the severity of the NCs and the resources available.

iv. Conclusion on the results of the inspections

The results of the 30 JIMs revealed a total of 366 findings, including 217 NCs, with no critical NCs identified. This indicates that none of the inspected manufacturers posed an immediate risk to public health. However, all inspections resulted in at least one NC, highlighting that full compliance remains uncommon.

The most frequently observed NCs were related to:

- Quality Management System – General Requirements – Identified in 63% of inspections, particularly in document management, change control, and regulatory strategy;

- Label and Instructions for Use – Found non-compliant in 63% of inspections, with issues such as missing information, language requirements, and lack of clarity;
- Product Realisation – Found in 56% of inspections, with deficiencies in supplier control, manufacturing processes, and traceability;
- Post-Market Surveillance – Non-compliant in 53% of inspections, often due to incomplete plans, missing data collection procedures, and outdated reports;
- Risk Management – Also non-compliant in 53% of inspections, mainly due to incomplete risk analyses and outdated documentation;
- Measurement, Analysis & Improvement – Found in 47% of inspections, with issues in complaint handling, CAPA processes, internal audits, and vigilance reporting;
- Management of Resources – Found in 47% of inspections, with frequent issues related to PRRC responsibilities, training documentation, and equipment maintenance;
- Verification and Validation – Identified in 43% of inspections, with deficiencies in clinical evaluation, biocompatibility, usability studies, and process validation;
- Conformity Assessment – Found non-compliant in 37% of inspections, often due to errors in the Declaration of Conformity, missing procedures, and incorrect CE marking.

The variability in the number and type of NCs across inspections reflects differences in manufacturer compliance and inspection approaches. Following the inspections, CAPA plans were requested and reviewed to address identified NCs, with some Member States applying additional enforcement measures such as warnings or fines.

VIII. Recommendations

i. Recommendations for Manufacturers

In order to improve regulatory compliance, manufacturers are encouraged to focus on the areas listed below. These recommendations are based on the non-compliances observed during the JIM campaign and may not be representative of the whole sector. Attention is drawn to the fact that manufacturers must follow all requirements listed in EU regulations as well as in national legislation, even if they were not highlighted in this report.

1. Quality Management System – General Requirements

- Implement robust procedures for document control, including version management, retention periods, and backup strategies for electronic records.
- Strengthen change control procedures with clear criteria for determining the significance of changes and guidance on when to notify the notified body.
- Maintain an up-to-date strategy for regulatory compliance, including references to current standards and applicable national legislation.

Schedule and document periodic reviews of the QMS to ensure ongoing suitability and effectiveness.

2. Labelling and Instructions for Use (IFU)

- Ensure that labelling and IFUs are available in all required national languages for the markets where the devices are distributed.
- Review IFUs for completeness, clarity, and consistency with the technical documentation.
- Verify that warnings and precautions are aligned with identified risks and that the intended population is clearly defined.
- Include all required harmonised symbols and ensure label readability across device formats.

3. Product Realisation

- Improve oversight of suppliers and subcontractors by maintaining complete lists, conducting regular audits, and establishing comprehensive quality agreements.
- Enhance manufacturing process controls, including contamination prevention, incoming material checks, and clear documentation of production steps.
- Strengthen traceability systems to allow tracking from raw materials to finished devices and vice versa.

4. Post-Market Surveillance (PMS)

- Develop and maintain PMS plans and reports that meet Annex III requirements, including proactive data collection, literature reviews, and analysis of similar devices.
- Define clear timelines and procedures for PMS activities and ensure consistent data collection across all markets.

5. Risk Management

- Conduct comprehensive risk analyses that include all relevant risks identified through clinical evaluation, literature, IFU warnings, and professional experience.
- Document and verify the effectiveness of risk control measures, and regularly update the risk management report.

6. Measurement, Analysis & Improvement

- Review and update procedures for complaints handling, ensuring clear links to NCs and timelines for evaluating serious incidents.
- Strengthen the CAPA process by ensuring root cause analysis and verification of effectiveness are systematically documented.
- Ensure internal audit procedures prevent conflicts of interest, cover all planned topics, and result in timely reporting.
- Clarify and reinforce vigilance reporting procedures, including trend detection and timely notification of reportable events.

7. Management of Resources

- Ensure the PRRC role is clearly defined in job descriptions, supported by documented qualifications, and properly registered in Eudamed.
- Maintain training records, develop specific annual training plans, and ensure job descriptions reflect current responsibilities and competencies.
- Improve equipment management, including maintenance schedules, temperature monitoring, and validation of measuring instruments.

8. Verification and Validation

- Maintain up-to-date clinical and biocompatibility evaluations, including plans, reports, and justification for test exclusions.
- Provide evidence to demonstrate device equivalence according to section 3 of Annex XIV.
- Ensure validations (e.g. sterilisation) are complete and properly documented.

9. Conformity Assessment

- Review the DoC for accuracy and completeness according to Annex IV of the regulations.
- Implement and follow procedures for establishing the DoC, and ensure it is signed by authorised personnel.
- Verify that certificates cover the full scope of device application and that CE marking is correctly applied.

ii. Recommendations for Notified Bodies

The JIM campaign highlighted several recurring areas of non-compliance among manufacturers, all of which were marketing devices that require a conformity assessment from a notified body (NB). Indeed, no manufacturer was placing only class I MDs or class A IVDs on the market. As key actors in the conformity assessment process, NBs are encouraged to consider the following recommendations to reinforce regulatory compliance and support harmonisation across the EU:

- Maintain a balanced and risk-based approach to conformity assessment: NBs should apply a proportionate level of scrutiny during conformity assessment, with particular attention to areas where non-compliances were frequently observed.
- Ensure continued compliance of manufacturers throughout the whole certification cycle: As observed during this campaign, many NCs were found in inspections of manufacturers whose QMS and devices were already certified by a NB. Sufficient resources dedicated to surveillance audits, and attention to changes, are essential to detect any new or preexisting NC.
- Ensure that manufacturers apply corrections to all their technical files: NBs apply sampling methods to evaluate manufacturers' technical files. When NCs are found the manufacturer is expected to correct them. However, if the manufacturer fails to apply these corrections to unsampled technical files, NCs may remain despite the certificate being issued.
- Strengthen collaboration with CAs and designating authorities: NBs should maintain open channels of communication with national CAs and designating authorities, especially when serious or systemic issues are identified, to ensure coordinated oversight and follow-up.

iii. Recommendations for Competent Authorities

Inspections are an important tool for market surveillance and are mandated by the medical devices regulations. To improve the consistency and effectiveness of inspections:

- Dedicate sufficient resources to medical devices inspections, including enough human resources (inspectors, experts and support staff) to cover their national market as well as to participate in joint inspections.
- Support training of inspectors: Continue efforts to train inspectors on harmonised inspection frameworks, such as the one developed in JAMS 2.0 WP 6, or the MD/IVD University initiative developed in JAMS 2.0 WP 8.

iv. Recommendations for future projects and harmonisation efforts

JAMS 1.0 laid the foundation upon which JAMS 2.0 WP 6 could be built. These two projects greatly helped harmonising the inspection practices between CAs. However, we observe that there are still important differences in the way inspections are conducted, such as in the way NCs are listed and graded. This means that there is still room to improve and strive for more harmonisation.

Building on the experience of this campaign of JIMs, the following recommendations can be made for future projects and harmonisation efforts at Union level:

- Secure budget to continue performing JIMs after the conclusion of JAMS 2.0: Joint inspections represent a very useful tool to enhance cooperation between CAs, to share experience and expertise between inspectors and to train junior inspectors, and to harmonise practices between inspectorates. These achievements risk eroding without constant maintenance through the organisation of new JIMs.
- Expand joint inspections to other economic operators: Apply the joint inspection framework to authorised representatives, importers, and distributors, as currently taking place in WP 6, and to other actors such as custom-made device manufacturers, sponsors and investigators of clinical investigations/performance studies, or system and procedure pack producers.
- Organise inspections of manufacturers located outside the Union: Initiatives like this campaign of JIMs are important to guarantee that economic operators remain compliant, but a significant proportion of the market is made of non-EU manufacturers. Making sure that they are held to the same standard as EU-based manufacturers is essential to ensure a level playing field.
- Refine inspection templates and tools: Update and standardise inspection templates (especially inspection checklists and reporting tools) based on lessons learned.

- Encourage balanced sampling: In future campaigns, aim for a more representative sample of manufacturers, including SMEs and IVD manufacturers, to better reflect the diversity of the sector.
- Develop guidance on NC classification: Consider drafting EU-level guidance and training on how to classify and group NCs to reduce discrepancies between inspectors and Member States.

IX. Acknowledgments

The authors would like to express their sincere gratitude to all those who contributed to the successful completion of this report.

Special thanks go to the reviewers who provided valuable feedback, helping to ensure the clarity, accuracy, and relevance of the document.

We are grateful to the dedicated inspectors who participated in the joint inspections that form the basis of this report. Their expertise and collaboration were essential to the success of this campaign.

We also acknowledge the manufacturers who agreed to take part in this project. Their cooperation during these out-of-the-ordinary inspections is greatly appreciated.

Finally, we thank the European Commission and HaDEA for co-funding this project. Their support made it possible to carry out this initiative and promote harmonisation efforts across Member States.