8th notified bodies survey on certifications and applications (MDR/IVDR)

Survey results of the 8th NB survey with data status 29 February 2024 (small and medium dataset)

17 May 2024
Disclaimer

• This document was produced in the frame of the SC 2021 P3 03 under the DG SANTE Framework contract (FWC SANTE/2021/OP/0002) for evaluation, impact assessment, monitoring and other related services in relation to health and food policies.

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• This presentation includes data and knowledge available at the time of the publication. The study-related dashboard contains the latest information and updates (e.g. further insights, retrospective corrections reported by stakeholders). Data discrepancies between this presentation and the regularly updated dashboard are therefore possible.
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2. Survey results for medical devices
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# List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>FTE</td>
<td>Full Time Equivalent</td>
</tr>
<tr>
<td>IVDs</td>
<td>In-vitro diagnostic medical device(s)</td>
</tr>
<tr>
<td>MDs</td>
<td>Medical device(s)</td>
</tr>
<tr>
<td>NBs</td>
<td>Notified body / bodies</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>SMCS</td>
<td>Single Market Compliance Space</td>
</tr>
<tr>
<td>SME</td>
<td>Small and medium-sized enterprise</td>
</tr>
</tbody>
</table>
1. About the study, survey and datasets

- Study supporting the monitoring of availability of medical devices on the EU market
- NB survey overview
- Dashboard
- Preliminary notes on the survey
- Survey timeline
- Response rate
Study supporting the monitoring of availability of medical devices on the EU market

• **Aim:** To support monitoring and analyzing the availability of medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations from the perspectives of key stakeholders

• **Duration:** 2 December 2022 – 1 December 2025 (36 months)

• **Study team** (contact: medical.devices@goeg.at):
  - Gesundheit Österreich GmbH (Austrian National Public Health Institute) → project lead
  - Areté
  - Civic Consulting

Supported by experts from the medical devices sector
## NB survey overview

NB surveys already conducted by the study team

<table>
<thead>
<tr>
<th>NB Survey</th>
<th>Survey period (survey launch – survey closure)</th>
<th>Requested dataset*</th>
<th>Requested data</th>
<th>Response rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st NB survey</td>
<td>03/04/2023 - 05/05/2023</td>
<td>SD1 + MD1</td>
<td>from designation up to 31/03/2023</td>
<td>39 out of 39 NBs** 100%</td>
</tr>
<tr>
<td>2nd NB survey</td>
<td>12/05/2023 - 05/06/2023</td>
<td>SD2</td>
<td>from designation up to 30/04/2023</td>
<td>27 out of 39 NBs** ~ 70%</td>
</tr>
<tr>
<td>3rd NB survey</td>
<td>05/06/2023 - 19/06/2023</td>
<td>SD3</td>
<td>from designation up to 31/05/2023</td>
<td>22 out of 39 NBs** ~ 56%</td>
</tr>
<tr>
<td>4th NB survey</td>
<td>03/07/2023 - 28/07/2023</td>
<td>SD4 + MD2</td>
<td>from designation up to 30/06/2023</td>
<td>39 out of 39 NBs** 100%</td>
</tr>
<tr>
<td>5th NB survey</td>
<td>01/09/2023 - 06/10/2023</td>
<td>SD5</td>
<td>from designation up to 31/08/2023</td>
<td>40 out of 40 NBs** 100%</td>
</tr>
<tr>
<td>6th NB survey</td>
<td>03/11/2023 - 22/12/2023</td>
<td>SD6 + MD3 + LD1</td>
<td>from designation up to 31/10/2023</td>
<td>41 out of 41 NBs** 100%</td>
</tr>
<tr>
<td>7th NB survey</td>
<td>08/01/2024 - 05/02/2024</td>
<td>SD7</td>
<td>from designation up to 31/12/2023</td>
<td>45 out of 45 NBs** 100%</td>
</tr>
<tr>
<td>8th NB survey</td>
<td>04/03/2024 - 20/03/2024</td>
<td>SD8 + MD4</td>
<td>from designation up to 29/02/2024</td>
<td>45 out of 45 NBs** 100%</td>
</tr>
</tbody>
</table>

*Datasets:
- The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**. **Note**: From April to July 2023, it was asked monthly.
- The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
- The **large dataset** contains additional data asked to notified bodies **once a year**.

**designated under MDR and/or IVDR

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Survey results included in the published dashboard

8th NB survey results are presented in this PowerPoint presentation
Dashboard

- NB survey results are presented in the study-related dashboard
- Available at: Study supporting the monitoring of availability of medical devices on the EU market - European Commission (europa.eu)
Preliminary notes

• **Data content:**
  - The following slides show the results of the *8th NB survey conducted at the beginning of March 2024* with *requested data* from notified bodies designated under MDR and/or IVDR until *29 February 2024*.
  - These survey results are also compared with previous survey data (see data sources).

• **Data sources:**
  - Data collected between April 2023 and March 2024 by the study team
  - Data collected between February 2021 and October 2022 by the European Commission

• **Datasets:**
  - This presentation contains the results of the *small and medium datasets* collected in March 2024.

  - The **small dataset** is a small set of questions (6 indicators) asked to notified bodies *every two months*. 
    Note: From April to July 2023, it was asked monthly.

  - The **medium dataset** is a set of questions asked to notified bodies *every four months* concerning the activities they have been performing since their designation.

  - The **large dataset** (not surveyed in the 8th NB survey) contains additional data asked to notified bodies *once a year*.
Timeline for the 8th NB survey
(conducted in March 2024 with requested data from designation up to 29/02/2024)

45 notified bodies designated under MDR and/or IVDR
(Data status: 1 March 2024)

4 March 2024
survey sent

13 March 2024
1st friendly reminder

15 March 2024
initial deadline

18 March 2024
2nd friendly reminder

20 March 2024
survey closed

March/April 2024
data validation

Final result
45 responses
(100% response rate)

Note: Out of 45 notified bodies, 33 NBs are designated under the MDR only, 10 NBs are designated under both the MDR and IVDR, and 2 NBs are designated under the IVDR only.
Response rate for the 8th NB survey
(conducted in March 2024 with requested data from designation up to 29/02/2024)

45 out of 45 notified bodies replies received (100% response rate)

Note: Out of 45 notified bodies, 33 NBs are designated under the MDR only, 10 NBs are designated under both the MDR and IVDR, and 2 NBs are designated under the IVDR only.
2. Survey results for medical devices

Note:

• Thousands separators are represented as dots or blank space (not comma) in the graphs.

• Datasets:

   🌟 The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**. **Note:** From April to July 2023, it was asked monthly.

   🌏 The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.

   🚀 The **large dataset** (not surveyed in the 8th NB survey) contains additional data asked to notified bodies **once a year**.
MDD/AIMDD Certificates by Annex (data status: April 2022)

Total valid MDD/AIMDD certificates by Annex

- Annex 2/II (excluding point 4): 12,461
- Annex 2. 4/II.4: 5,769
- Annex 4/IV: 961
- Annex 5/V: 5,597
- Annex VI: 148

Total: 25,034
MDR applications filed and certificates issued (sum of Annexes)

Notes: February 2024: Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20
* The data shown comes from the medium data set M – except for 2 NBs where the total number of applications filed was derived from the small data set S since they could not provide the data per Annex.
• Δ (Delta) = Difference in MDR Applications / MDR Certificates from one survey to the next one
• Applications filed: This number includes all applications filed (syn. lodged) so far according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
• Certificates issued: This number includes certificates issued so far (from designation up 29/02/2024) under the MDR.
MDR applications and certificates by annex survey comparison

Applications survey comparison

February 2024 MDR Applications: 20,424*

Certificates survey comparison

February 2024 MDR Certificates: 6,978

Notes:
• Designated NBs for MD: 43; NBs that included Annex XVI products in the numbers provided: 20
• * The data shown comes from the medium data set (applications and certificates by Annex: 2 NBs could not provide the application information by Annex; hence the total number of applications is higher -> see number in the small data set)
• ** Change in methodology of counting by a few NBs, leading to decreases.

Applications lodged by annex: This number includes all applications lodged (syn. filed) by annex according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e. applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.

Certificates issued by annex: This number includes certificates issued so far (from designation up to 29/02/2024) under the MDR by annex.
MDR applications and certificates by type (QMS vs Product) – survey comparison

Note QMS Applications and Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.

Note PRODUCT Applications and Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.

Total number of applications lodged for changes received for already MDR issued certificates: **2,535**
Specific additional procedures according to Annex IX (II)

Applications filed requiring consultation procedure

- Devices incorporating a medicinal substance: 498
- Devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable: 100
- Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body:
  - Applications filed: 39
  - Thereof certificates issued: 12

Notes:
* The data shown comes from the medium data set – except for 2 NBs where the total number of applications filed was derived from the small data set since they could not provide the data per Annex.

February 2024

MDR Applications:
Total number of applications filed by Annex: 20,424

MDR Certificates:
Total number of certificates by Annex: 6,978
Average timeframe to written agreement signed

Average timeframe between application lodged and written agreement signed:

In the majority of the cases (62%), it takes less than 2 months from an application lodged to a written agreement signed.

Note: Data of 40 notified bodies
### MDR applications - reason for refusal

#### Reasons for refusal

<table>
<thead>
<tr>
<th>Reason</th>
<th>October 22</th>
<th>March 23</th>
<th>June 23</th>
<th>October 23</th>
<th>February 2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong conformity assessment procedure</td>
<td>12</td>
<td>13</td>
<td>54</td>
<td>61</td>
<td>13</td>
</tr>
<tr>
<td>Insufficient notified body resources</td>
<td>35</td>
<td>45</td>
<td>37</td>
<td>47</td>
<td>63</td>
</tr>
<tr>
<td>Other</td>
<td>32</td>
<td>74</td>
<td>103</td>
<td>81</td>
<td>176</td>
</tr>
<tr>
<td>Wrong qualification of product/classification of device</td>
<td>24</td>
<td>80</td>
<td>126</td>
<td>140</td>
<td>176</td>
</tr>
<tr>
<td>Application not complete</td>
<td>24</td>
<td>66</td>
<td>66</td>
<td>205</td>
<td>205</td>
</tr>
<tr>
<td>Outside the scope of notified body's designation</td>
<td>208</td>
<td>304</td>
<td>304</td>
<td>304</td>
<td>460</td>
</tr>
</tbody>
</table>

**February 2024**

**Main reasons**
- “Outside the scope of NB’s designation” (55%)
- “Application not complete” (17%)

### Notes:
- Comparison of reasons for refusal in October 2022, March 2023, June 2023, October 2023 and February 2024.
- **Applications can have multiple reasons for refusal; the total number shown is derived from the small data set and differ from the figures in the medium data set.**
- **February 2024:** data of 25 NBs; some stated “other” reasons in February 2024: “Withdrawal/cancellation of the application by the manufacturer”, “customer did not respond on e-mails and phone calls”, “PMS plan not at MDR level”, “multiple presence of critical suppliers in different states”, “Unresolved non-conformities”, “unacceptable language”
- **October 2023:** data of 24 NBs; some stated „other“ reasons in October 2023: “Withdrawal by the customer”, “Unresolved non-conformities”, “Customer refused audit”, “incorrect codes”, “not a medical device”, “PMS plan not at MDR level”, “client stopped communication”, “the client rejected the offer”, customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “This product did not meet essential requirements despite comprehensive feedback by the NB”
- **June 2023:** data of 24 NBs; some stated “other” reasons in June 2023: “Withdrawal by the customer”, “Unresolved non-conformities”, “PMS plan not at MDR level”, “customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “This product did not meet essential requirements despite comprehensive feedback by the NB”
- **March 2023:** data of 19 NBs; some stated “other” reasons in March 2023: “withdrawal of the application by the manufacturer - not ready for MDR, due to economic reasons, etc.”, “customer did not respond on e-mails and phone calls”, “manufacturer was unable to prove the given indication of use was achieved without pharmacological and metabolical means by ingredients”, “customer has voluntarily requested to cancel MDR application.”, “This product did not meet essential requirements despite comprehensive feedback by the NB”, “PMS plan not at MDR level”

### Application refusals**:
- **October 2022:** 232
- **March 2023:** 269
- **June 2023:** 328
- **October 2023:** 367
- **February 2024:** 454

### Total number of MDR applications:
- **October 2022:** 8120
- **March 2023:** 11,418
- **June 2023:** 13,177
- **October 2023:** 17,846*
- **February 2024:** 20,424*

* The data shown comes from the medium data set – except for 2 NBs where the total number of applications filed was derived from the small data set since they could not provide the data per Annex.

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* MD
Completeness of submissions

Completeness of submissions expressed by notified bodies* (in number of NBs) (Annex VII, Section 4.3) – survey comparison

<table>
<thead>
<tr>
<th></th>
<th>Less than 25 %</th>
<th>25-50 %</th>
<th>51-75 %</th>
<th>More than 75 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 22</td>
<td>15</td>
<td>5</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Mar 23</td>
<td>21</td>
<td>12</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>June 23</td>
<td>18</td>
<td>12</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Oct 23</td>
<td>13</td>
<td>16</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Feb 24</td>
<td>17</td>
<td>16</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

% of submissions with completeness rate > 50%
- 13% (of NBs) in March 2023
- 23% (of NBs) in February 2024

Incomplete submissions remain high*

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information
Time to reach a new certificate (QMS vs QMS+PRODUCT)

- For 47% of NBs: 6-12 months to issue a new QMS certificate
- For 46% of NBs: ≥ 13 months (max: 24 months)

MDR QMS+PRODUCT certificates: longer time
- For 40% of NBs: 13-18 months to issue a new product certificate
- For 77% of NBs: ≥ 13 months

Notes:
* The data shown comes from the medium data set – except for 2 NBs where the total number of applications filed was derived from the small data set since they could not provide the data per Annex.
• This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.
• Some NBs have not issued a certificate yet, so the indicated time frame is an estimation.
• One NB stated that time from agreement to certificate varies a lot.
• One NB stated to observe time periods to be increasing.
Questions on Annex XVI products
(products with no intended medical purpose that fall under the scope of the MDR)

<table>
<thead>
<tr>
<th>Question</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received requests to sign a written agreement for a conformity assessment procedure of an Annex XVI product, in accordance with the condition established in Article 2(1) of Regulation (EU) 2022/2346, from 01/01/2023 up to 29/02/2024</td>
<td>72</td>
</tr>
<tr>
<td>Received requests to sign a written agreement for a conformity assessment procedure of an Annex XVI product, in accordance with the condition established in Article 2(2) of Regulation (EU) 2022/2346, from 01/01/2023 up to 29/02/2024</td>
<td>147</td>
</tr>
<tr>
<td>Received requests to sign a written agreement for a conformity assessment procedure of an Annex XVI product, in accordance with the condition established in Article 2(3) of Regulation (EU) 2022/2346, from 01/01/2023 up to 29/02/2024</td>
<td>39</td>
</tr>
<tr>
<td>Estimation of transit of MDD certificates for Annex XVI products to the MDR without maintaining the medical purpose for the covered devices</td>
<td>146</td>
</tr>
</tbody>
</table>

Notes:
- 19 out of 43 NBs entered "0" for all questions relating to Annex XVI products.
Questions on Annex XVI products
(products with no intended medical purpose that fall under the scope of the MDR)

From which **date** can the NB work on Annex XVI products?

- **27 out of 43** NBs can already work on Annex XVI products from 22 June 2023 on
- **16 out of 43** NBs have stated another date and/or reason for delay

Data of 43 NBs designated under MDR

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/09/2023</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>29/09/2023</td>
<td>no reason indicated; NB is already working on Annex XVI products</td>
</tr>
<tr>
<td>01/01/2024</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>12/04/2024</td>
<td>need of a formal authorisation from the Designation Authority</td>
</tr>
<tr>
<td>01/12/2024</td>
<td>insufficient capacity</td>
</tr>
<tr>
<td>31/12/2024</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>01/01/2025</td>
<td>insufficient capacity</td>
</tr>
<tr>
<td>12/12/2035</td>
<td>need of a formal authorisation from the Designation Authority</td>
</tr>
<tr>
<td>01/09/2023</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>22/12/2023</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>01/04/2024</td>
<td>need of a formal authorisation from the Designation Authority</td>
</tr>
<tr>
<td>01/08/2024</td>
<td>need of a formal authorisation from the Designation Authority</td>
</tr>
<tr>
<td>23/12/2024</td>
<td>insufficient capacity</td>
</tr>
<tr>
<td>01/01/2025</td>
<td>need to develop internal procedures</td>
</tr>
<tr>
<td>01/01/2025</td>
<td>insufficient capacity</td>
</tr>
<tr>
<td>Date unclear</td>
<td>need of a formal authorisation from the Designation Authority</td>
</tr>
</tbody>
</table>

**Reasons for delay**

- no reason indicated; 1; 6%
- need of a formal authorisation from the Designation Authority; 5; 31%
- need to develop internal procedures; 6; 38%
- insufficient capacity; 4; 25%
MDR applications filed and refused, written agreements signed

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of total certification applications lodged so far (from designation up to 29/02/2024) in accordance with Annex VI section 4.3 of MDR*</td>
<td>21,004</td>
</tr>
<tr>
<td>Number of written agreements signed (from designation up to 29/02/2024)**</td>
<td>12,324</td>
</tr>
<tr>
<td>Number of applications refused for MDR (from designation up to 29/02/2024)</td>
<td>454</td>
</tr>
</tbody>
</table>

Notes:

- **Designated NBs for MD:** 43
- **Applications lodged:** This number includes all applications lodged (syn. filed) so far according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.
MDR number of QMS / product certificates issued

Note QMS Certificates: This relates to Annex IX Chapter I or Annex XI Part A according to MDR.

Number of QMS certificates issued (total and first time only)

Total number of QMS certificates issued for MDR (from designation up to 29/02/2024): 4,740
Total number of QMS certificates issued for MDR (from designation up to 29/02/2024) - thereof first time only: 2,910

Number of product certificates issued (total and first time only)

Total number of product certificates issued for MDR (from designation up to 29/02/2024): 2,272
Total number of product certificates issued for MDR (from designation up to 29/02/2024) - thereof first time only: 1,632

Note PRODUCT Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.
Estimation - Scope of the (AI)MDD certificates covered by MDR applications (on average)

- 10 out of 43 NBs (23%) reported that 41-60% of the MDR applications cover the scope of (AI)MDD certificates
- 26 out of 43 NBs (60%) indicated that MDR applications cover more than 60% of the scope of (AI)MDD certificates.

Calculation:
- meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

Meaning of average:
- MDR application n°1 covers 1 product on 10 (MDD cert) = 10%
- MDR application n°2 covers 50 products on 100 (MDD cert) = 50%
- MDR application n°3 covers 4 products on 12 (MDD cert) = 33%
=> so average % = 31% => between 21% and 40%
Survey comparison – March 2023 to February 2024

Number of total certification applications lodged incl. no. of applications with issued certificates in accordance with Annex VI section 4.3 of MDR

- from designation up to 29/02/2024
- from designation up to 31/12/2023
- from designation up to 31/10/2023
- from designation up to 30/08/2023
- from designation up to 30/06/2023
- from designation up to 31/05/2023
- from designation up to 30/04/2023
- from designation up to 31/03/2023

Number of written agreements signed

- from designation up to 29/02/2024
- from designation up to 31/12/2023
- from designation up to 31/10/2023
- from designation up to 30/08/2023
- from designation up to 30/06/2023
- from designation up to 31/05/2023
- from designation up to 30/04/2023
- from designation up to 31/03/2023

Number of applications refused for MDR

- from designation up to 29/02/2024
- from designation up to 31/12/2023
- from designation up to 31/10/2023
- from designation up to 30/08/2023
- from designation up to 30/06/2023
- from designation up to 31/05/2023
- from designation up to 30/04/2023
- from designation up to 31/03/2023

Notes:
- Designated NBs for MD for all survey rounds: 43; different response rates for each survey round (see info box above).

This survey comparison includes data from the small dataset (6 indicators) collected between April 2023 and March 2024 by the study team:
- Survey #1: data from designation up to 31/03/2023 (100% response rate)
- Survey #2: data from designation up to 30/04/2023 (~70% response rate)
- Survey #3: data from designation up to 31/05/2023 (~56% response rate)
- Survey #4: data from designation up to 30/06/2023 (100% response rate)
- Survey #5: data from designation up to 30/08/2023 (100% response rate)
- Survey #6: data from designation up to 31/10/2023 (100% response rate)
- Survey #7: data from designation up to 31/12/2023 (100% response rate)
- Survey #8: data from designation up to 29/02/2024 (100% response rate)

Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.
Survey comparison – March 2023 to February 2024

This survey comparison includes data from the small dataset (6 indicators) collected between April 2023 and March 2024 by the study team:
- **Survey #1**: data from designation up to 31/03/2023 (100% response rate)
- **Survey #2**: data from designation up to 30/04/2023 (~ 70% response rate)
- **Survey #3**: data from designation up to 31/05/2023 (~ 56% response rate)
- **Survey #4**: data from designation up to 30/06/2023 (100% response rate)
- **Survey #5**: data from designation up to 30/08/2023 (100% response rate)
- **Survey #6**: data from designation up to 31/10/2023 (100% response rate)
- **Survey #7**: data from designation up to 31/12/2023 (100% response rate)
- **Survey #8**: data from designation up to 29/02/2024 (100% response rate)

Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

Notes:
- Designated NBs for MD for all survey rounds: 43; different response rates for each survey round (see info box above)
- * Increase of 13% from survey #1 to #2; In survey #4, the questionnaire was redesigned, and the question on “total number of certificates issued” (in addition to “first time only”) was included in the small dataset.
- ** Change in methodology of counting by few NBs compared to previous surveys.
- The redesign of the questionnaire helped the NBs to better assess the number of first-time only certificates. Therefore, the numbers of the previous surveys might be an overestimation.
Survey comparison – March 2023 to February 2024
Estimation - Scope of the (AI)MDD certificates covered by MDR applications (on average)

**Calculation:**
- Meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert

**Meaning of average:**
- MDR application n°1 covers 1 product on 10 (MDD cert) = 10%
- MDR application n°2 covers 50 products on 100 (MDD cert) = 50%
- MDR application n°3 covers 4 products on 12 (MDD cert) = 33%

=> so average % = 31% => between 21% and 40%

---

**From designation up to 31/03/2023:**
- <20%: 8
- 21% to 40%: 6
- 41% to 60%: 6
- 61% to 80%: 8
- >80%: 12

**From designation up to 30/04/2023:**
- <20%: 8
- 21% to 40%: 9
- 41% to 60%: 8
- 61% to 80%: 11
- >80%: 10

**From designation up to 31/05/2023:**
- <20%: 8
- 21% to 40%: 10
- 41% to 60%: 9
- 61% to 80%: 11
- >80%: 11

**From designation up to 30/06/2023:**
- <20%: 8
- 21% to 40%: 9
- 41% to 60%: 9
- 61% to 80%: 9
- >80%: 10

**From designation up to 30/08/2023:**
- <20%: 8
- 21% to 40%: 8
- 41% to 60%: 8
- 61% to 80%: 11
- >80%: 10

**From designation up to 31/10/2023:**
- <20%: 8
- 21% to 40%: 10
- 41% to 60%: 11
- 61% to 80%: 10
- >80%: 11

**From designation up to 31/12/2023:**
- <20%: 8
- 21% to 40%: 10
- 41% to 60%: 10
- 61% to 80%: 8
- >80%: 11

**From designation up to 29/02/2024:**
- <20%: 8
- 21% to 40%: 10
- 41% to 60%: 10
- 61% to 80%: 8
- >80%: 11
3. Survey results for in vitro diagnostic medical devices

Note:

- Thousands separators are represented as dots or blank space (not comma) in the graphs.

- Datasets:
  - The **small dataset** is a small set of questions (6 indicators) asked to notified bodies **every two months**. 
    - Note: From April to July 2023, it was asked monthly.
  - The **medium dataset** is a set of questions asked to notified bodies **every four months** concerning the activities they have been performing since their designation.
  - The **large dataset** contains additional data asked to notified bodies **once a year**.
IVDD Certificates by date of expiry
(data status: October 2022)

IVDD Data
Data from survey of October 2022
(20 out of 21 replies received from NB designated under IVDD)

Tot. valid IVDD certificates 1.551
IVDR applications lodged and certificates issued

Notes:
- Designated NBs for IVDR: 12
- Δ (Delta) = Difference in IVDR Applications / IVDR Certificates from one survey to the next one
- Applications lodged: This number includes all applications lodged (syn. filed) so far according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
- Certificates issued: This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR.
IVDR applications and certificates by annex – surveys comparison

Applications survey comparison

February 2024 IVDR Applications: 1,634

Certificates survey comparison

February 2024 IVDR Certificates: 798

Notes:

• **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024). i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.

• **Certificates issued by annex:** This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR by annex.
IVDR applications and certificates by annex

February 2024
IVDR Applications: 1,634
IVDR Certificates: 798

Notes:

- **Applications lodged by annex**: This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in NANDO to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.

- **Certificates issued by annex**: This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR by annex.

- **Class D devices** are included in the total number of applications/certificates.
Class D devices applications and certificates

Notes:
• **Applications lodged by annex:** This number includes all applications lodged (syn. filed) by annex according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing IVDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.
• **Certificates issued by annex:** This number includes certificates issued so far (from designation up to 29/02/2024) under the IVDR by annex.
• Data for Annex XI has changed compared to previous surveys because of a change in methodology of counting byNBs.

**February 2024**
- IVDR Applications: 1,634
- IVDR Certificates: 798

**February 2024:**
- Class D devices Applications: 370
- Class D devices Certificates: 173

Class D devices applications/certificates by annex, February 2024

<table>
<thead>
<tr>
<th>Annex IX(I&amp;III)</th>
<th>Applications_February 2024</th>
<th>Certificates_February 2024</th>
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<tr>
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<td>71</td>
<td>26</td>
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<tr>
<td>Annex IX(II)</td>
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<td>147</td>
</tr>
<tr>
<td>Annex X</td>
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<td>0</td>
</tr>
</tbody>
</table>
IVDR applications - reason for refusal

Notes:
- This graph compares the total number of applications that have been refused under IVDR by reason of refusal in October 2022, March 2023, June 2023, October 2023 and February 2024.
- Applications can have multiple reasons for refusal.
- March 2023: Reasons were indicated by one NB only. “Other” reasons: “application withdrawn by the manufacturer (not yet ready for the IVDR, due to economic reasons,…)”
- June 2023: Reasons were indicated by two NBs only. “Other” reasons: “nonconformities not solved”, “withdrawal of client”, “assessment resulted in negative outcome”
- October 2023: Reasons were indicated by two NBs only. “Other” reasons: “nonconformities not solved”, “withdrawal of client”, “assessment resulted in negative outcome”
- February 2024: Reasons were indicated by three NBs only. “Other” reasons: “nonconformities not solved”, “withdrawal of client”, “assessment resulted in negative outcome”

February 2024
IVDR Applications: 1.634
IVDR Certificates: 798

Total number of IVDR application refusals:
- October 2022: 2
- March 2023: 49
- June 2023: 16
- October 2023: 6
- February 2024: 7

Main reasons for refusals: “Other” (57%)
Completeness of submissions

Completeness of submissions expressed by notified bodies (in percent of notified bodies) (Annex VII, Section 4.3) – survey comparison

% of submissions with completeness rate > 50%: for 3 out of 12 NBs in February 2024

Submissions largely incomplete*

* Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information
Time to reach a certificate

Notes:
- Data of 12 NBs
- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under IVDR.
- One NB specifically pointed out that this is an estimate as they have not issued certificates yet.

### Time to reach IVDR certificate (QMS vs QMS+PRODUCT)

- **%**
  - 67% of NBs: 6-12 months to issue a new QMS certificate
  - 25% of NBs: 13-18 months

**IVDR QMS+PRODUCT certificates:** longer time
- 75% of NBs: 13-18 months
- 17% of NBs: 19-24 months

---

February 2024
IVDR Applications: 1,634
IVDR Certificates: 798
IVDR applications filed and refused, written agreements signed

- **Designated NBs for IVD:** 12
- **Applications lodged:** This number includes all applications lodged (syn. filed) so far according to IVDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Space to the date of the survey up to 29/02/2024), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included.
- **Written agreements signed:** This refers to the number of written agreements (contracts) between a NB and a manufacturer signed by both parties.

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**Number of total certification applications lodged so far (from designation up to 29/02/2024) in accordance with Annex VII section 4.3 of IVDR**: 1703

**Number of written agreements signed (from designation up to 29/02/2024)**: 845

**Number of applications refused for IVDR (from designation up to 29/02/2024)**: 7
**IVDR Number of QMS / product certificates issued**

- **Note QMS Certificates:** This relates to Annex IX Chapter I or Annex XI according to IVDR.

- **Note PRODUCT Certificates:** This relates to Annex IX Chapter II, Annex X or Annex XI according to IVDR.

---

**Number of QMS certificates issued**  
(total and first time only)

- Total number of QMS certificates issued for IVDR (from designation up to 29/02/2024)
- Total number of QMS certificates issued for IVDR (from designation up to 29/02/2024) - thereof first time only

**Number of product certificates issued**  
(total and first time only)

- Total number of product certificates issued for IVDR (from designation up to 29/02/2024)
- Total number of product certificates issued for IVDR (from designation up to 29/02/2024) - thereof first time only
Survey comparison – March 2023 to February 2024

Number of total certification applications lodged incl. no. of applications with issued certificates in accordance with Annex VII section 4.3 of IVDR

Number of written agreements signed

Number of applications refused for IVDR

This survey comparison includes data from the small dataset (6 indicators) collected between April and November 2023 by the study team:

- **Survey #1**: data from designation up to 31/03/2023 (100% response rate)
- **Survey #2**: data from designation up to 30/04/2023 (~70% response rate)
- **Survey #3**: data from designation up to 31/05/2023 (~56% response rate)
- **Survey #4**: data from designation up to 30/06/2023 (100% response rate)
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- **Survey #8**: data from designation up to 29/02/2024 (100% response rate)

Surveys #2 and #3 did not reach 100% response rate. In this case, for the NBs that did not respond, data from previous surveys were included in the total for each indicator.

Notes:

- Designated NBs for survey #1 to #5: 10
- Designated NBS for survey #6 to #8: 12
Survey comparison – March 2023 to February 2024

This survey comparison includes data from the small dataset (6 indicators) collected between April and November 2023 by the study team:

- **Survey #1**: data from designation up to 31/03/2023 (100% response rate)
- **Survey #2**: data from designation up to 30/04/2023 (~ 70% response rate)
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Notes:
- Designated NBs for survey #1 to #5: 10
- Designated NBS for survey #6 to #8: 12
Thank you

Contact for questions: medical.devices@goeg.at