



# Notified Bodies Survey on certifications and applications (MDR/IVDR)

Survey results with data status 31 March 2023

*July 2023*

# 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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- Some data may still need validation check and might change.

# 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:**

Gesundheit Österreich  
GmbH

Gesundheit Österreich GmbH (Austrian National Public Health Institute) → project lead

Areté  
The Agri-food  
Intelligence  
Company

Areté

CIVIC  
CONSULTING

Civic Consulting

Supported by experts from the medical devices sector

# Preliminary notes on the survey

- **Data content:**

- The following slides show the results of the survey **conducted at the beginning of April 2023** with **requested data** from notified bodies designated under MDR/IVDR **until 31<sup>st</sup> March 2023**.

- **Data sources:**

- Data collected in April 2023 by the study team
- Data collected between February 2021 and October 2022 by the European Commission

# List of abbreviations

| Abbreviation | Meaning   |
|--------------|---|
| AIMDD        | Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices |
| IVD          | In-vitro diagnostic medical device(s)   |
| IVDD         | Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices   |
| IVDR         | Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In Vitro Diagnostic Medical Device Regulation)            |
| MD           | Medical device(s)   |
| MDD          | Council Directive 93/42/EEC of 14 June 1993 concerning medical devices  |
| MDR          | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)                                |
| NB           | Notified body   |
| QMS          | Quality Management System   |

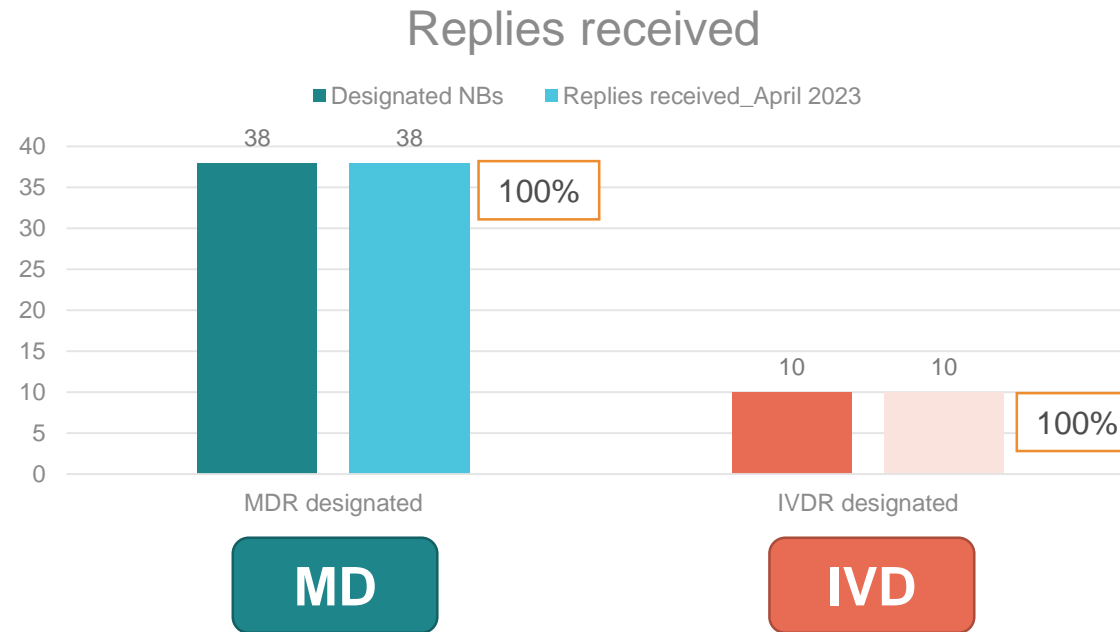
# Survey timeline



# Survey on certifications and applications

## Response rate

**39 out of 39 notified bodies replies received (100% response rate)**

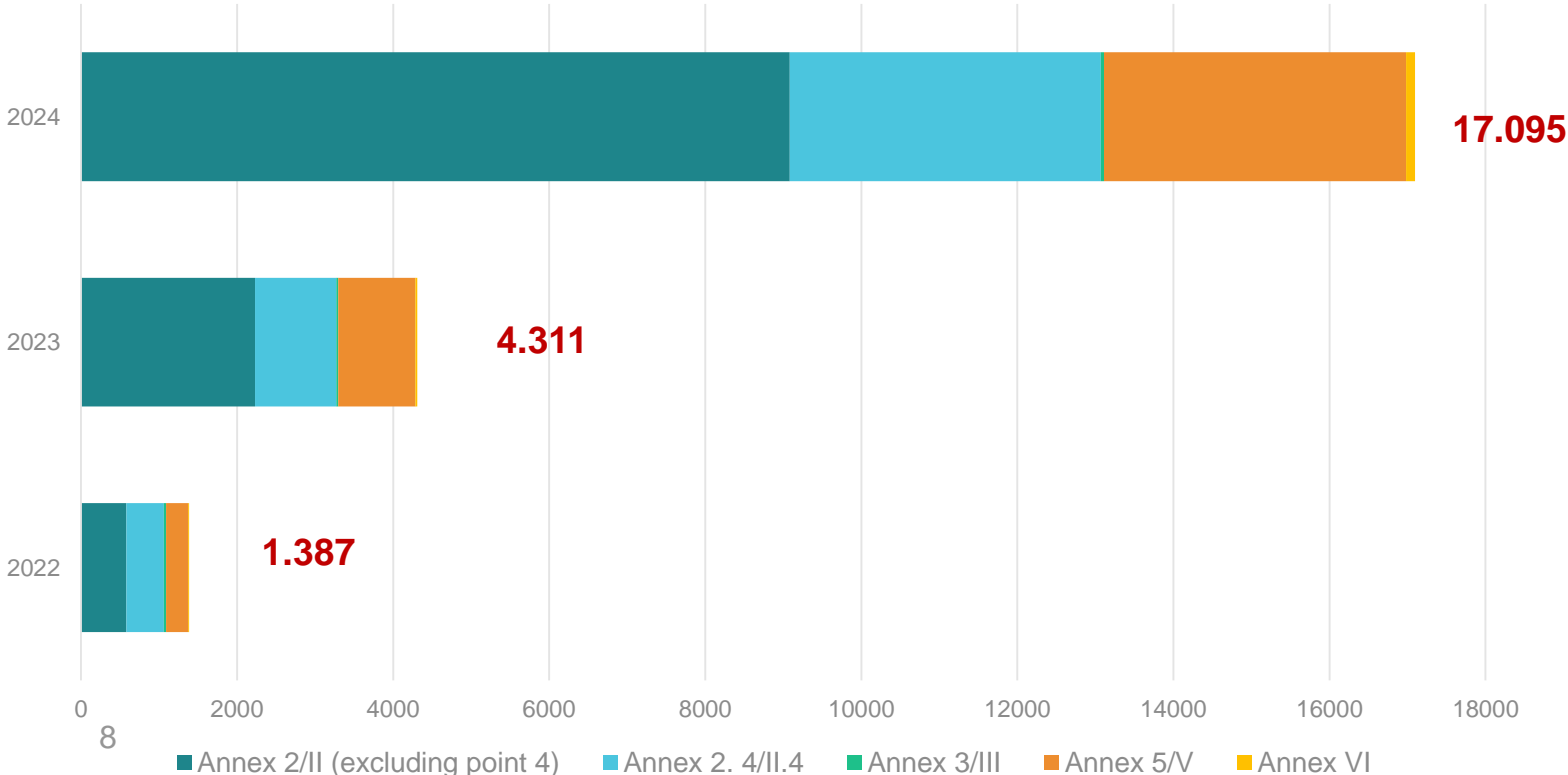


*Note: Out of 39 notified bodies, 29 NBs are designated under the MDR, 9 NBs are designated under both the MDR and IVDR, and one NB is designated under the IVDR.*

# Survey on certifications and applications

## MDD/AIMDD Certificates – October 2022

MDD/AIMDD valid certificates breakdown by date of expiry



**MDD/AIMDD Data**  
**Data from survey of October 2022**

|                  |                          |
|------------------|--------------------------|
| AIMDD designated | 16 replies out of 18 NBs |
| MDD designated   | 45 replies out of 49 NBs |

**Total valid MDD/AIMDD certificates (excluded Annex 4/IV\*): 22.793\*\***

\* Annex 4/IV certificates :363  
 \*\* 24.073 in April 2022

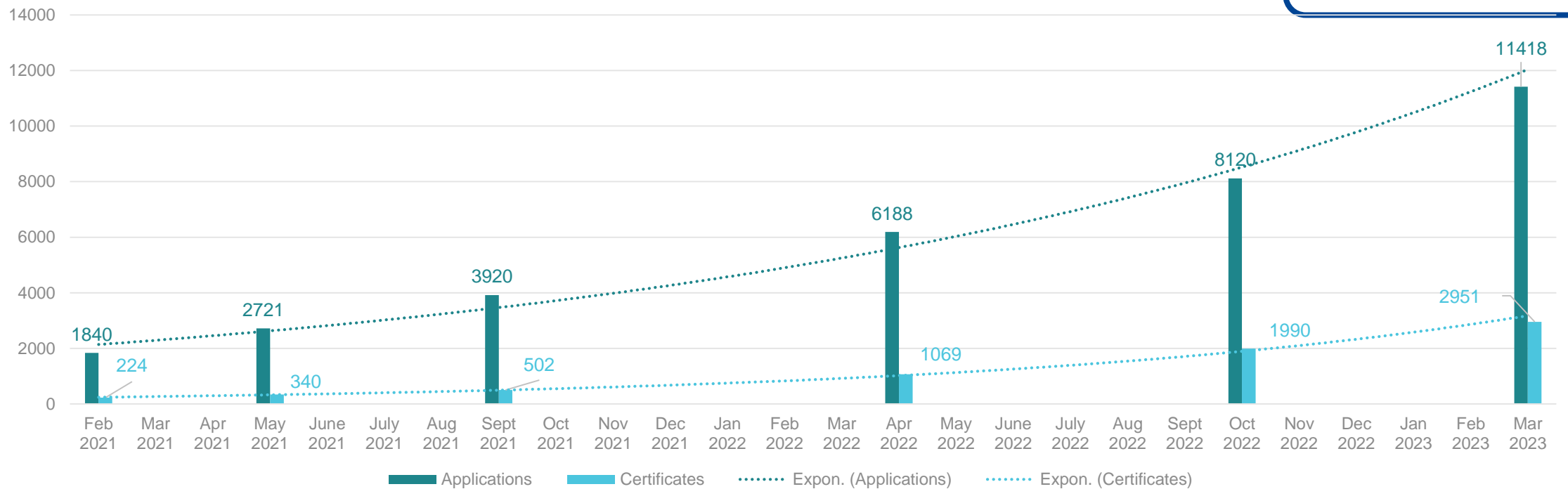


# Survey on certifications and applications

MDR Data (1/8)

March 2023  
 MDR Applications: 11418  
 MDR Certificates: 2951

## MDR applications filed and certificates issued



Designated NBs for MD: 38  
 Active\* NBs: 31  
 Average number of certificates issued per active NB: 95  
 October 2022: Total valid MDD/AIMDD certificates (excluded Annex 4/IV\*\*): 22793\*\*\*

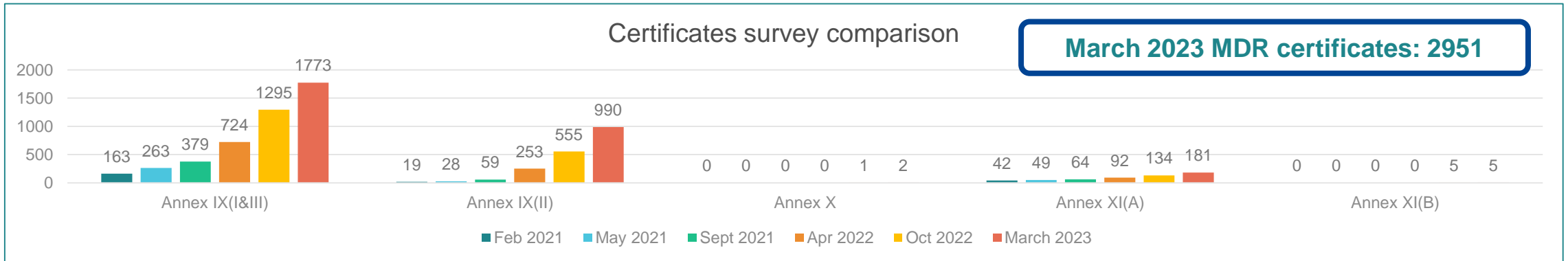
\*Active NBs are NBs that have issued certificates  
 \*\* Annex 4/IV certificates: 363  
 \*\*\* 24073 in April 2022



# Survey on certifications and applications

MDR Data (2/8)

## MDR applications and certificates by annex – survey comparison

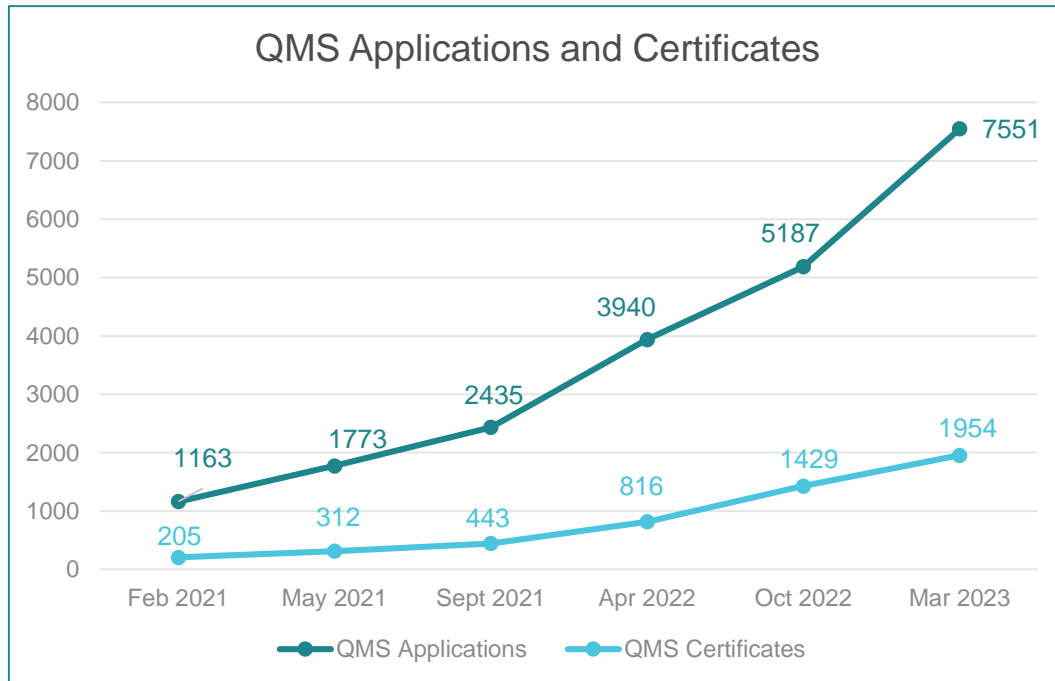


# Survey on certifications and applications

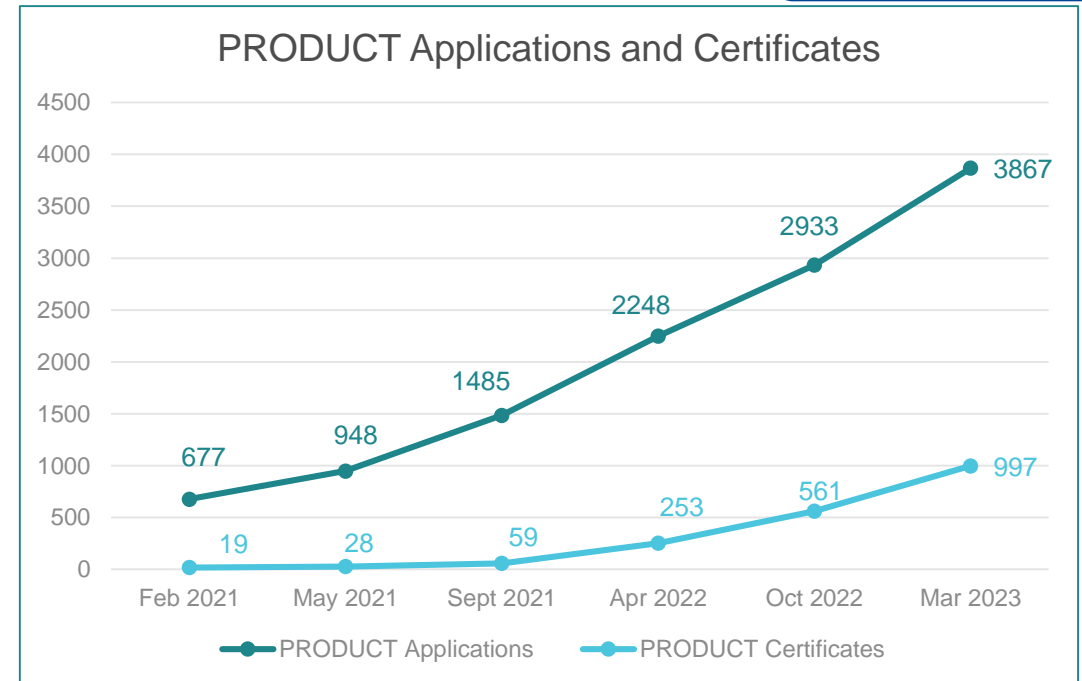
MDR Data (3/8)

## MDR applications and certificates by type (QMS vs Product) – survey comparison

March 2023 MDR applications: 11418



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

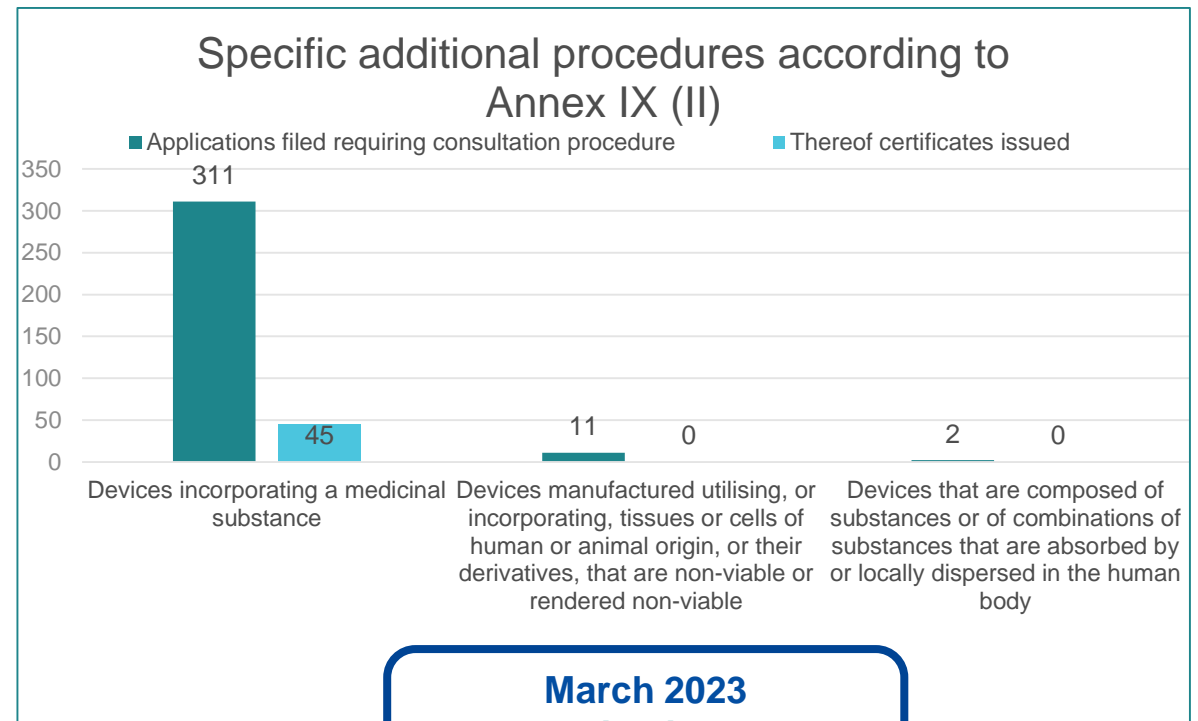
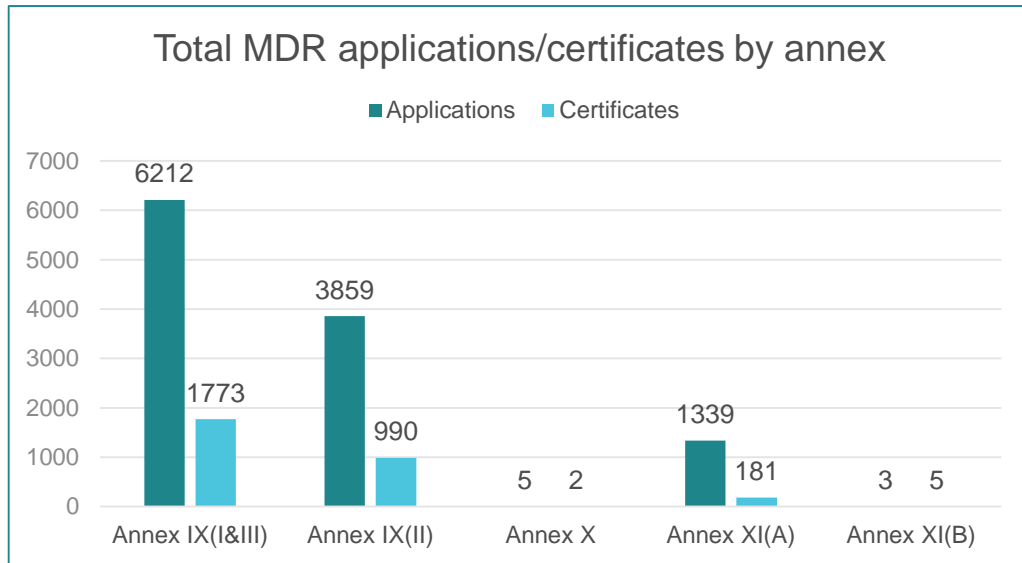


PRODUCT Applications and Certificates: This relates to Annex IX Chapter II, Annex X or Annex XI Part B according to MDR.

# Survey on certifications and applications

MDR Data (4/8)

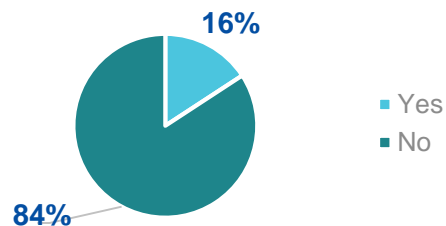
## MDR certificates and applications - March 2023



**March 2023**  
**MDR Applications: 11418**  
**MDR Certificates: 2951**

Note: The total number of applications filed also includes applications for which certificates have been already issued.

Annex XVI products included in the numbers provided above:



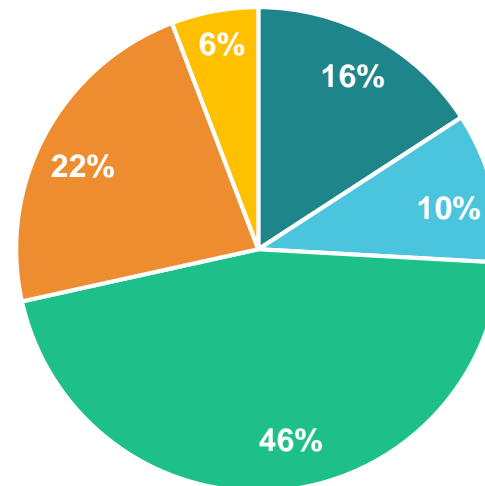
# Survey on certifications and applications

MDR Data (5/8)

Total number of applications lodged for changes received for already MDR issued certificates: **1812**

March 2023 MDR applications: 11418

Average timeframe between application lodged and written agreement signed:



On average it takes 2-3 months from an application lodged to a written agreement signed

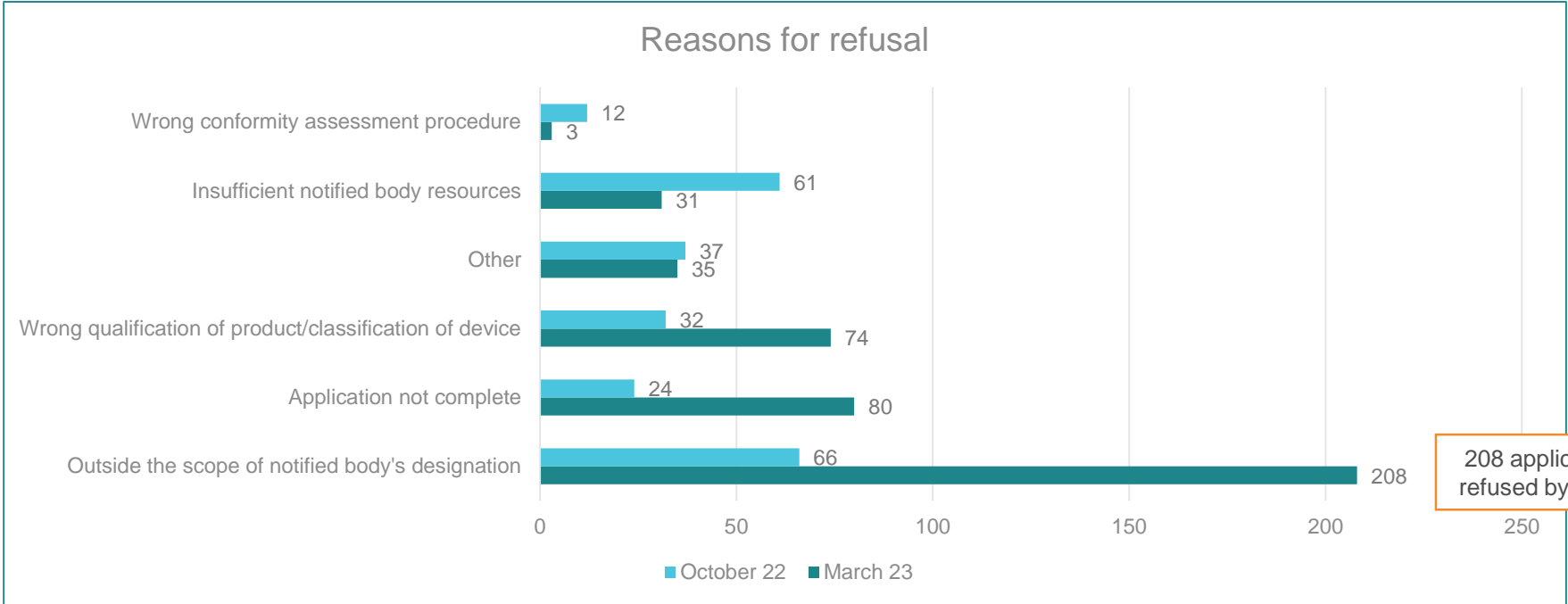
*Note: Data of 33 notified bodies*

■ 1-2 weeks ■ 3-4 weeks ■ 2 to 3 months ■ 3 to 6 months ■ >6 months

# Survey on certifications and applications

MDR Data (6/8)

## MDR applications - reason for refusal



October 2022  
Total number of MDR Applications: 8120

March 2023  
Total number of MDR Applications: 11418

208 applications refused by 7 NBs

Note: Comparison of reasons for refusal in October 2022 and March 2023  
Data of 19 notified bodies for March 2023

Some stated "other" reasons:

"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 metabolic means by ingredients", "customer has voluntarily requested to cancel MDR application.", "product did not meet essential requirements despite comprehensive feedback by the NB", "PMS plan not at MDR level"

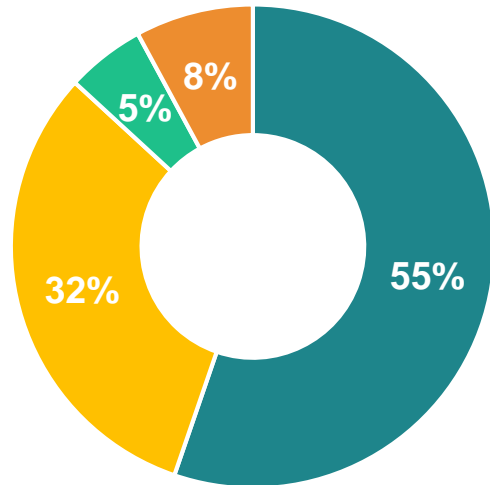
# Survey on certifications and applications

## Completeness of submissions and time to reach a new certificate (QMS vs QMS+PRODUCT)

MDR Data (7/8)

Completeness of submissions (Annex VII, Section 4.3)

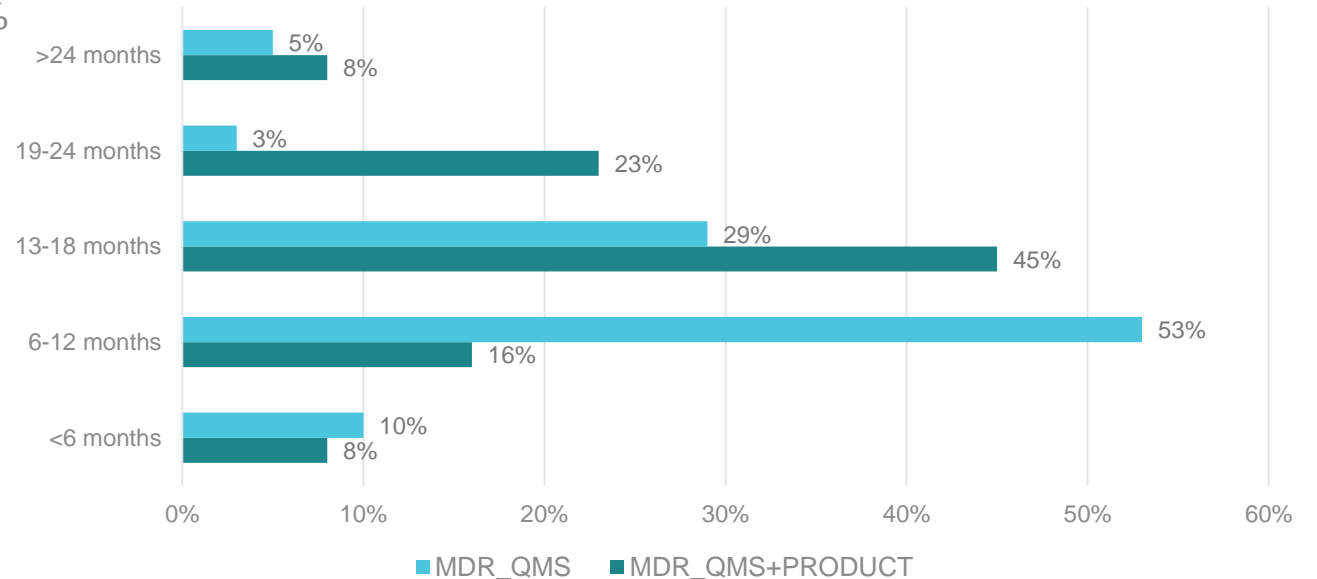
■ Less than 25 % ■ 25-50 % ■ 51-75 % ■ More than 75 %



Several submissions deemed 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

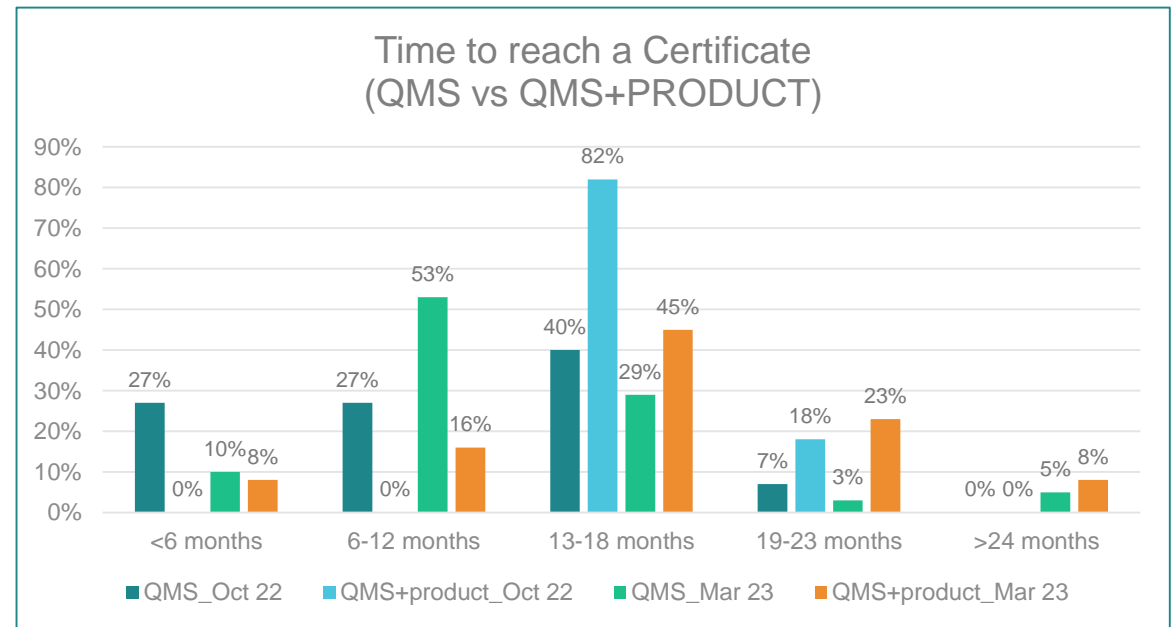
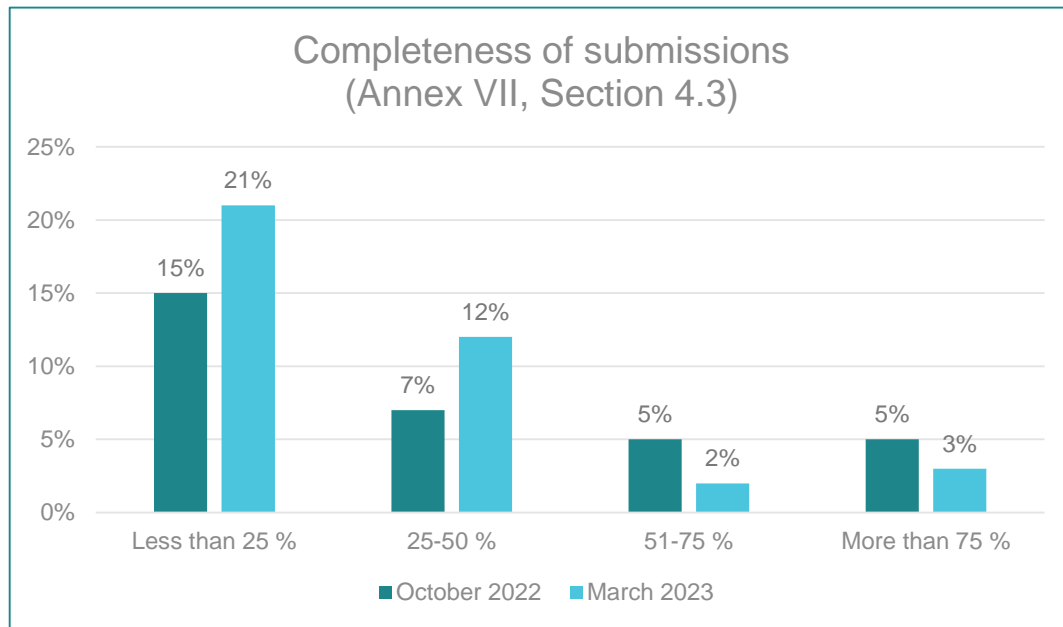
Time to reach a Certificate (QMS vs QMS+PRODUCT)



# Survey on certifications and applications

## Completeness of submissions and time to reach a new certificate (QMS vs QMS+PRODUCT)

MDR Data (8/8)



Incomplete submissions on the rise\*

\*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

Note: Comparison of data concerning the time to reach a certificate regarding QMS certificates and QMS+product certificates from October 2022 and March 2023

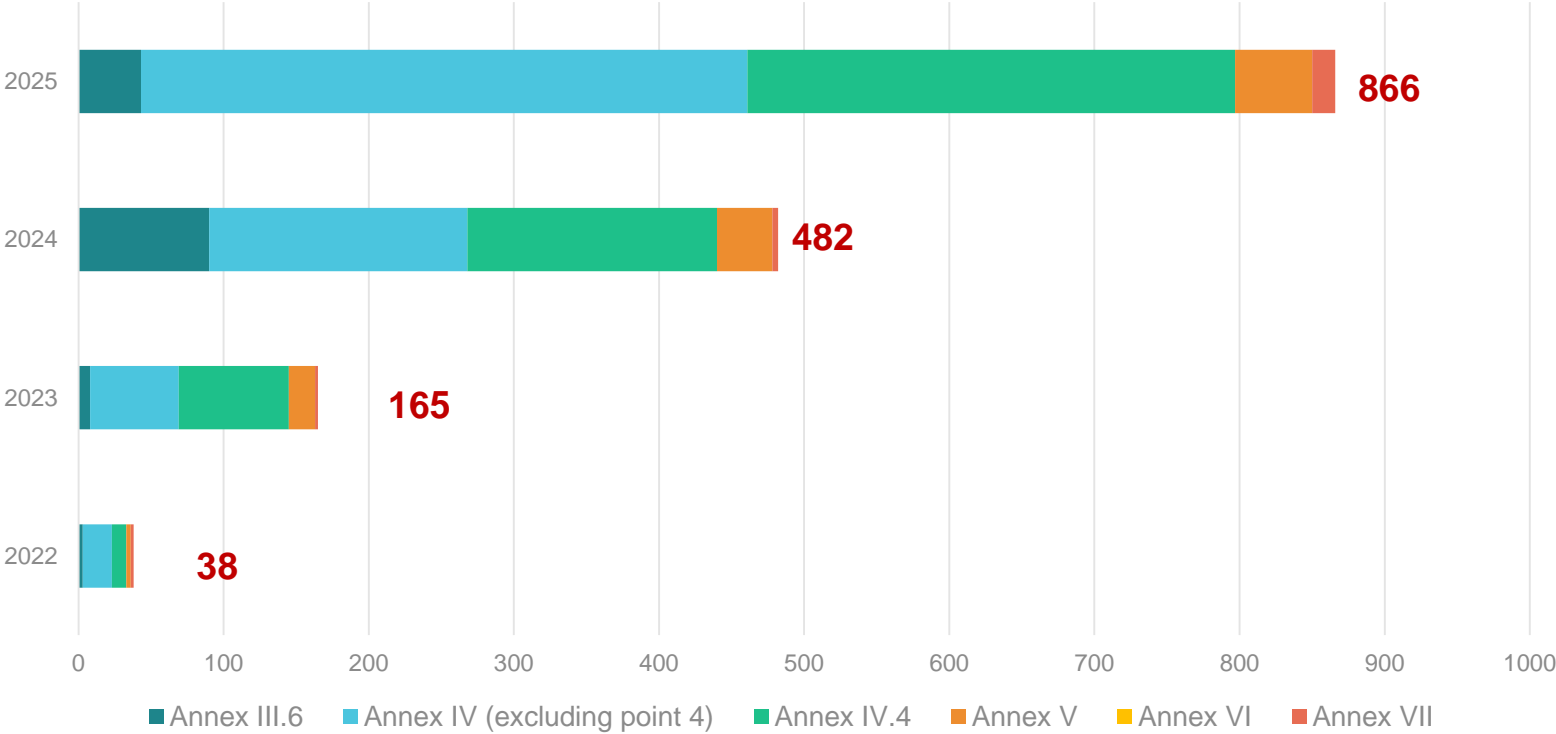


# Survey on certifications and applications

## IVDD Certificates by date of expiry – October 2022

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

IVDD valid certificates breakdown by date of expiry



**Tot. valid IVDD certificates 1551**

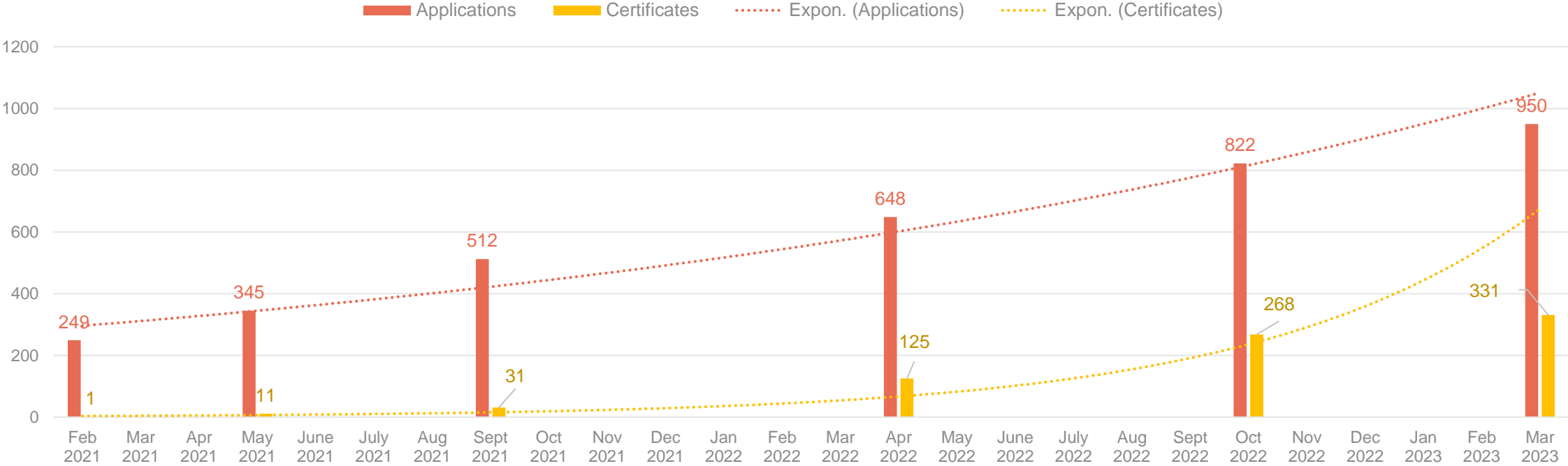
# Survey on certifications and applications

## IVDR applications filed and certificates issued

IVDR Data (1/5)

**March 2023**  
**IVDR Applications: 950**  
**IVDR Certificates: 331**

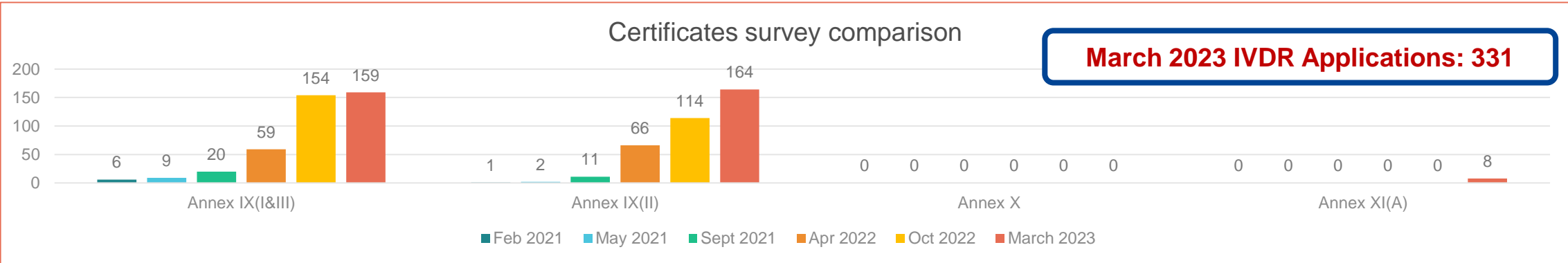
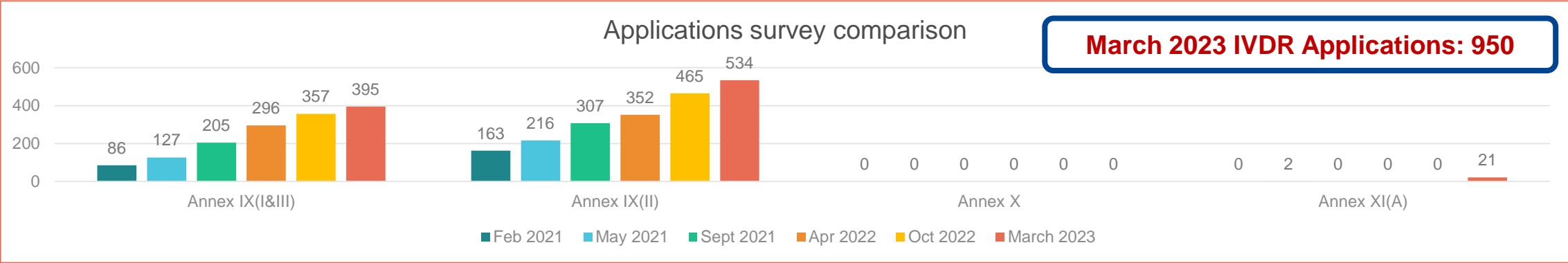
IVDR Development Total



# Survey on certifications and applications

IVDR Data (2/5)

## IVDR applications and certificates by annex – surveys comparison

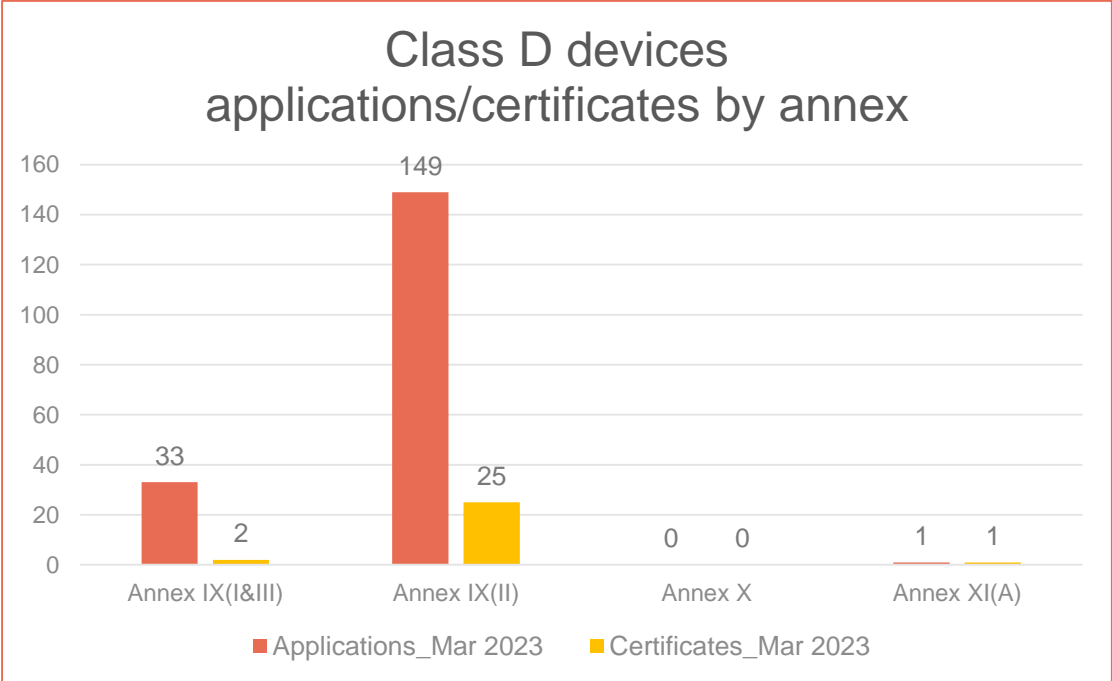
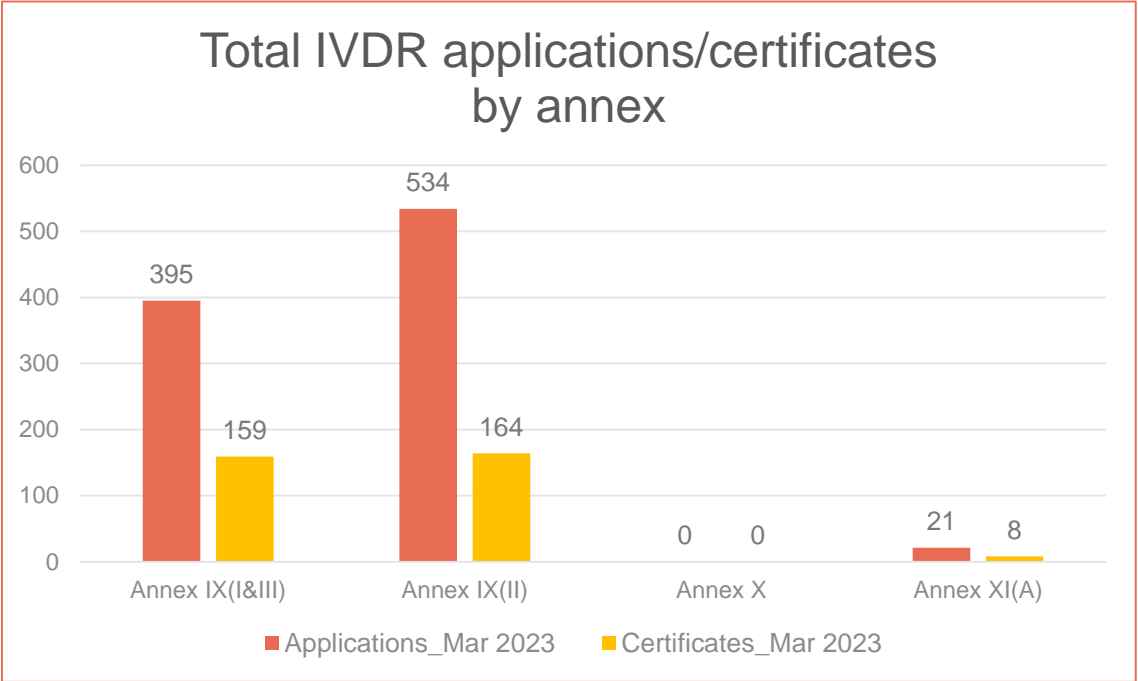


# Survey on certifications and applications

## IVDR applications and certificates by annex

March 2023  
 IVDR Applications: 950  
 IVDR Certificates: 331

IVDR Data (3/5)



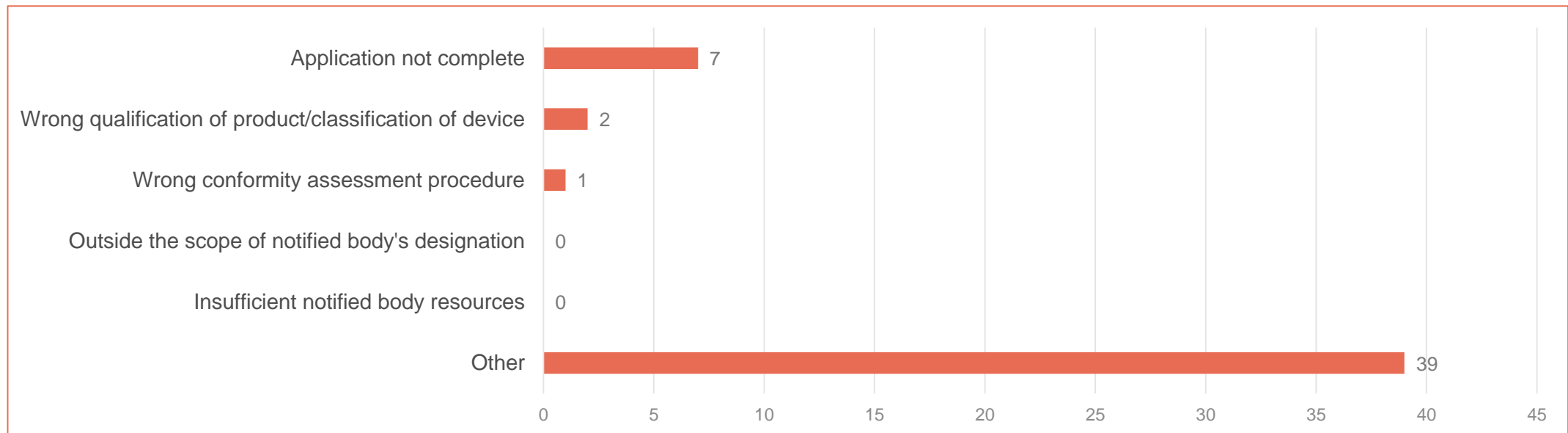
Notes:

- The total number of applications filed also includes applications for which certificates have been already issued.
- Class D devices are included in the total number of applications/certificates.

# Survey on certifications and applications

IVDR Data (4/5)

## IVDR applications - reason for refusal



*Note:*

- *Data were entered by one notified body only.*
- *“Other” reasons: “application withdrawn by the manufacturer (not yet ready for the IVDR, due to economic reasons,...)”*

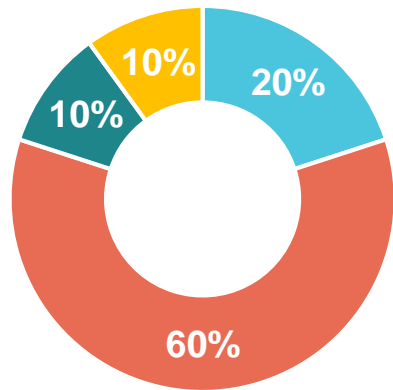
# Survey on certifications and applications

IVDR Data (5/5)

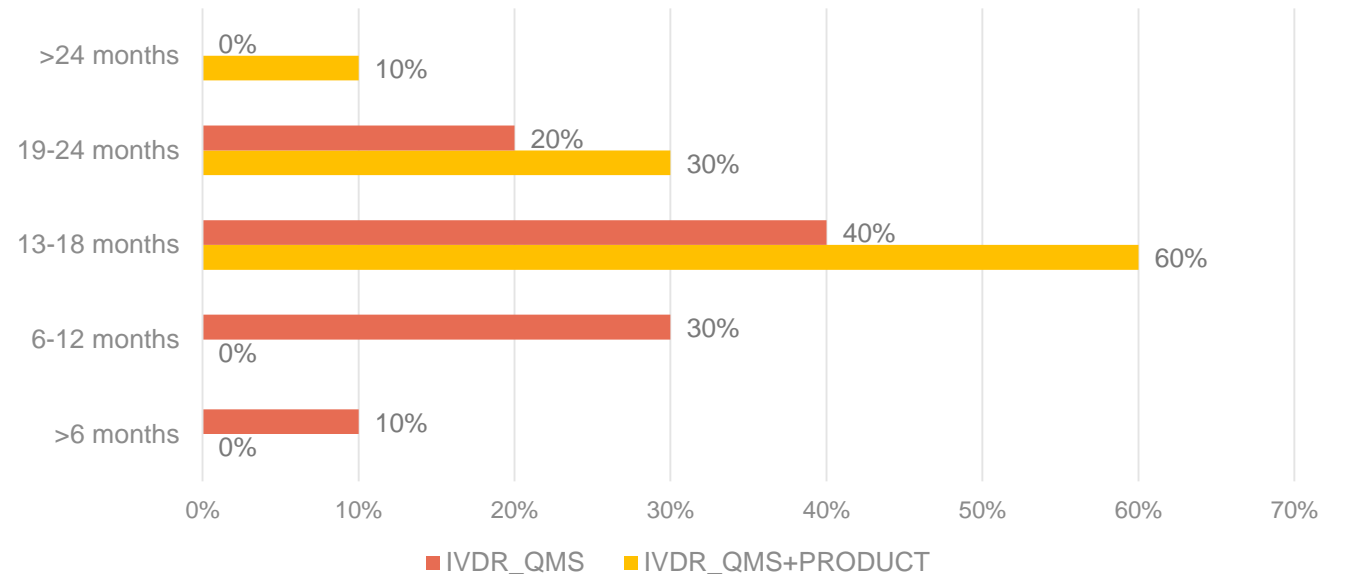
## Completeness of submissions and time to reach a certificate

Completeness of submissions  
(Annex VII, Section 4.3)

■ <25 % ■ 25-50 % ■ 51-75 % ■ >75 %



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



**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

# Thank you

Contact for questions: [medical.devices@goeg.at](mailto:medical.devices@goeg.at)



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