# *Annex VII Amendments*

Predictability of Notified Body Assessment under EU MDR 2017/745 and EU IVDR 2017/746

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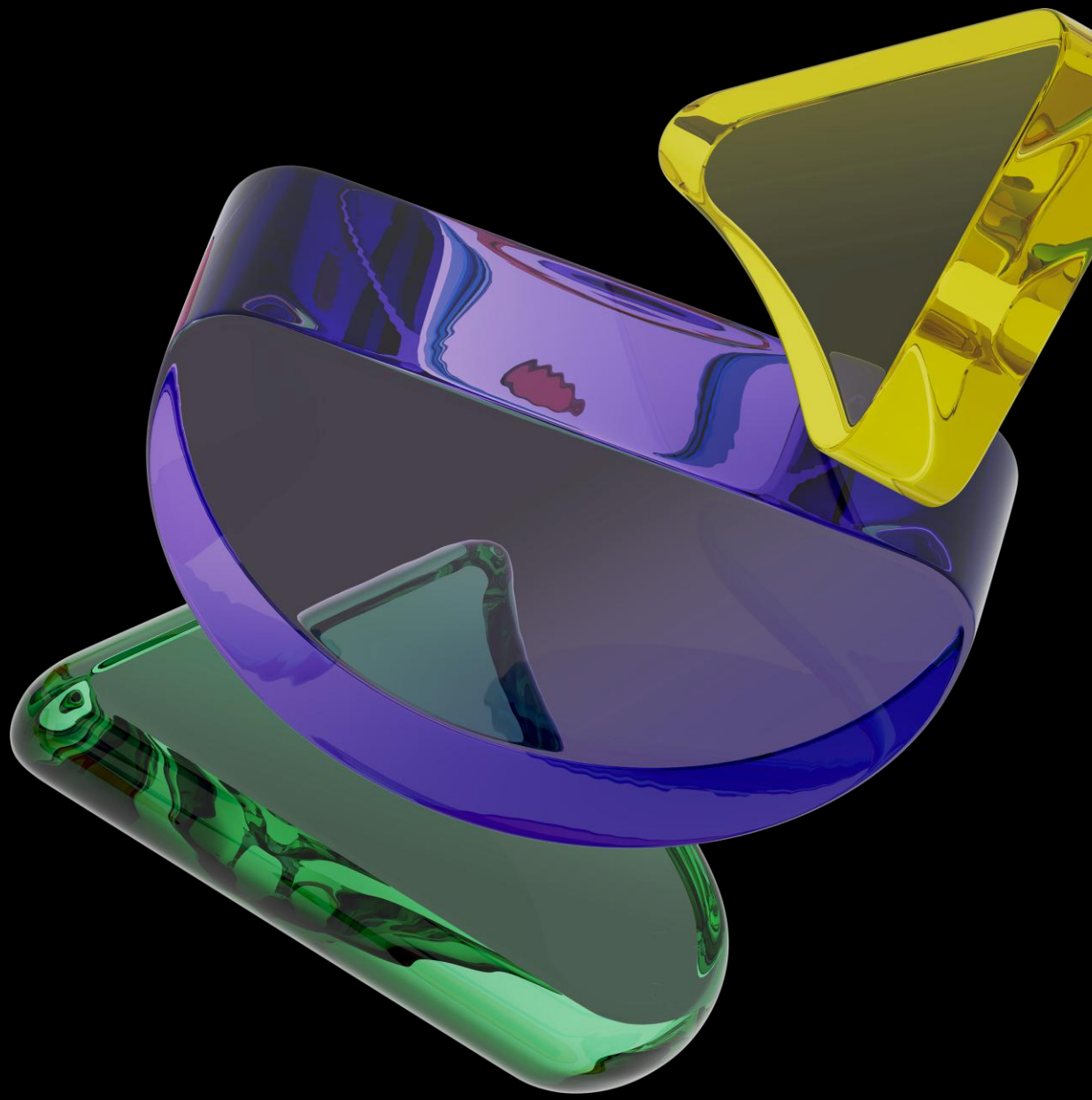

# Annex VII - Proposed revision

**Article 1 – Quotations**

- NBs to collect info related to the manufacturer, devices, subcontractors etc to be able to issue an accurate quote
- NBs quotation to include overall costs, typical costs for surveillance activities, travel, accommodation and any potential extra costs arising from assessment activities etc
- NBs to inform the manufacturer and justify any increases of the initially estimated costs
- Quotation to specify the agreed timelines for various conformity assessment activities

**Transitional timelines:** 3 months after entry into force

# Annex VII - Proposed revision

**Articles 2/3 – Timelines**

- Initial certification
- Changes

**Transitional timelines:** 3 months after entry into force (out of scope quotes issued before that)

| INITIAL CERTIFICATION Activity | Annex VII clauses | TIMELINE (Calendar Days) | CLOCK STOPS (nr) |
|---|---|---|---|
| Application review | 4.3. Application review and contract<br>4.4. Allocation of resources | 30 | 1 |
| QMS assessment | 4.5. Conformity assessment activities<br>4.6. Reporting<br>4.7. Final review | 120 | 3 |
| TD assessment | | 90 | 3 |
| Final decision and certificate issuance | 4.8. Decisions and Certifications | 15 | / |

The timelines will apply for future applications (new applications lodged after the end of the transitional period)

Timelines could be shorter if agreed with the manufacturer

**Careful planning of conformity assessment activities is pivotal!**

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4.2. Notified body quotations and pre-application activities is outside the scope (no timelines)

No limitations imposed to the structure of the application (e.g., one application for QMS+all TD or one single application covering QMS and one application for each TD)

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| Final decision and certificate issu | | 15 | / |

QMS and TD assessments can be carried out in parallel

Timelines start from when the NB initiates the first activity in relation to their conformity assessment process.

**QMS assessment:** the proposed timeline of 120 days for QMS assessment (MDR Annex VII 4.5.2) will start from Day 1 of the Stage 1 audit.

If the NB does not perform Stage 1 audit, it starts from Day 1 of the Stage 2 audit (or the MDR/IVDR QMS audit).

From that Day 1, all activities related to QMS assessment must be completed within the proposed 120 days with 3 clock-stops (to account for the gap between Stage 1 and Stage 2, CAPA process etc).

**TD assessment:** the proposed timeline of 90 days will start from when the NB starts the TD assessment for a given device. The time taken from the submission of the file to when the NB starts the initial review does not count towards the 90 days.

Once the TD assessment has started, the NB is expected to complete its TD assessment and final review within 90 days with 3 clock stops.

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| QMS assessment | 4.5. Conformity assessment activities<br>4.6. Reporting<br>4.7. Final review | 120 | 3 |
| TD assessment | | 90 | 3 |
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**Concerns**

**Timelines:**

- 90 days for TD assessment challenging for complex devices with multiple competencies involved (NBs proposed to extend to 150 days)
- Using external experts might be an issue

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| QMS assessment | 4.5. Conformity assessment activities<br>4.6. Reporting<br>4.7. Final review | 120 | 3 |
| TD assessment | | 90 | 3 |
| Final decision and certificate issuance | 4.8. Decisions and Certifications | 15 | / |

NBs asked for a clock-stop in the decision-making step

NBs that do final review + decision making together – 15 days is too short. NBs asked to extending it to 25 days

# Annex VII - Proposed revision

**Articles 2/3 – Timelines**

- Initial certification
- Changes

**Transitional timelines:** 3 months after entry into force (out of scope quotes issued before that)

| CHANGES Activity | TIMELINE (Calendar Days) | CLOCK STOPS (nr) |
|---|---|---|
| Assessment of change request | 30 | 3 |
| Conformity assessment activities and approval | 90 | |

**Concerns**

**Timelines:**

- When do the timelines start?
- 90 days: all changes are not equal (unfair on some changes and too long for simple changes). 90 days is very short
- 90 days timeline will impact in the NBs having to prioritise the change approvals over and above legacy device transitions and new applications
- 90 days would be very challenging as it also includes Final Review and Decision Making.

**Clock-stops:**

- A total of 3 clock-stops for the entire change approval process would be challenging.

**NB proposal**

**Timelines:**

Would prefer similar structure as initial assessment – based on the nature of the change:

- simple changes (one type of conformity assessment activity) 90 days;
- more complex changes (more than one type of conformity assessment activity) – 120 days (As initial, longest)

**Clock-stops:**

NBs propose 3 clock-stops per conformity assessment activity required to approve a change (QMS audit, TD assessment etc). EU Comm to consider this request.

# Annex VII - Proposed revision

**Article 4 – Monitoring of the duration and costs**

Significant new requirements for the NBs to monitor their timelines, costs and publish annual reports on specific metrics on their websites and provide those to EC.
Report on the below metrics by 30 April of every year (starting from 2028) (publish on BSI website and provide to the Commission)

**Transitional timelines:** 12 months after entry into force (out of scope quotes issued before that)

| **Timelines:** | **Costs:** |
|---|---|
| 1. % of conformity assessment activities completed within the timelines, (then minimum, maximum and median duration of activities)<br><br>2. % of conformity assessment activities for which a specific procedure was carried out | 1. minimum, maximum and median total cost of completed conformity assessment activities, in Euro;<br>2. median of the percentage of extra costs not estimated by the initial quotation, calculated on the total cost;<br>3. percentage of travel and accommodation costs, calculated on the total cost. |

# Annex VII - Proposed revision

**Articles 5-8 – Recertification**

- Added list of information to be submitted by the manufacturer to support the recertification of the quality system and product annex certificates.
- NBs to notify a manufacturer at least one year in advance of their certificate expiry. Once the information specified is submitted by the manufacturer, it is proposed that the NB must complete reviewing that information within 60 days, including clock stops.

**Transitional timelines:** re-certification reviews of certificates expiring before 1.5 years after entry into force

| RECERTIFICATION Activity | TIMELINE (Calendar Days) | CLOCK STOPS (nr) |
|---|---|---|
| Notification to manufacturer | 365 (before expiry date) | / |
| Review of documentation received | 60 | 2 |
| Decision and certificate | 15 | / |

# Questions?

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