

Questions and Answers document regarding the Implementation of the new Manufacturer Incident Report (MIR) Form

Version 1.0
May 2020

In December 2018, a **new Manufacturer Incident Reporting (MIR) form and related documentation** have been published at the European Commission website. The form introduced novel information requirements such as use of **IMDRF adverse event terms and codes** or **trending data based on relevant similar incidents**.

This first release of this Question and Answer (Q&A) document is intended to help companies to adapt their IT system to the new MIR form by indicating the main changes compared to previous MIR form and by tackling typical IT questions in the Annex.

This document will be complemented with further developments in particular as regards the transition to the MDR / IVDR Regulation and to the new Eudamed database. As regards the horizontal rules applicable in particular to vigilance requirements before the new Eudamed becomes available, a specific guidance document is under development.

The new MIR form became applicable from 1st January 2020 for the reporting of Incidents under both the EU Directives and the Regulations both for MDs and for IVDs:

- for **Incidents** under the AIMD/MDD/IVDD¹ (as defined in [MEDDEV 2.12/1 Guidelines on a medical devices vigilance system](#)) and
- for **Serious Incidents** under the MDR/IVDR.

This is reflected in the title of the document: *Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMD/MDD/IVDD)*. **Accordingly, whenever the MIR form refers to ‘incident’ it should read ‘serious incident’, i.e. reportable event, when the form is used to report under the MDR or IVDR.**

The current version of the [new MIR Form \(version 7.2.1\)](#) and the associated [helptext](#) and [XSD files](#) can be found on the European Commission website at: https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en (under MEDDEV guidance).

¹ Directive 90/385/EEC (‘AIMDD’), Directive 93/42/EEC (‘MDD’), and Directive 98/79/EEC (‘IVDD’)

A. Main changes introduced by the new MIR form

The European Competent Authorities and Industry representative organisations agreed to use codified information on incidents (adverse events in IMDRF terminology) for the reporting of incidents in advance of the date of application of the upcoming Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices (EU) ('MDR') and Regulation (EU) 2017/746 ('IVDR').

1. New adverse event terminologies to be implemented in the European incident reporting system

During the past number of years, the International Medical Device Regulators Forum (IMDRF) (<http://www.imdrf.org/>) has developed and published new terms and codes for adverse event reporting. It is anticipated that this internationally harmonised terminology will improve stakeholders ability to conduct detection, description, analysis of and information exchanges relating to risks and failures associated with medical devices and in vitro diagnostic medical devices, enabling faster responses by industry and authorities. Notably, the word 'adverse event' in the present context includes (serious) incident as defined in the EU (MDR art 2. definition 65, IVDR art 2. definition 68).

The IMDRF adverse event terminologies are scheduled to be implemented in the European vigilance reporting system with **a one-year transition period after their initial publication on IMDRF website** where they are publicly available at the following link:

<http://www.imdrf.org/documents/documents.asp>

2. Other main changes

The other main new elements that have been included in the MIR form relate to the request for trending data, more specifically the number of similar reportable incidents and the number of devices placed on the market related to the current year and the three previous ones.

The objective of this change is to provide the evaluating Member States with the necessary data (a nominator and a denominator) to enable them estimating the magnitude/ likelihood of the reported issue and hence possible public health risks associated with relevant reportable incidents.

B. Enforcement of IMDRF adverse events terminologies (terms and codes)

The European Competent Authorities and Industry representative organisations agreed to use internationally codified information on incidents and serious incidents (adverse events in IMDRF terminology) for the reporting of incidents in advance of the date of application of the upcoming Regulation (EU) ('MDR') and Regulation (EU) 2017/746 ('IVDR').

1. Structure of IMDRF adverse event terminologies and implementation dates

The IMDRF adverse event terminologies are structured in four areas and comprises seven subsets (Annexes A to G). The table 1 below provides the links to the different Annexes and reference mapping published by the IMDRF. The publication dates on the IMDRF website² and the dates of their enforcement in the EU (considering a one full year implementation period) are also indicated.

Table 1: The IMDRF adverse event terminologies (terms and codes)

| IMDRF Adverse Event Reporting Categories | Terms and codes | IMDRF publication dates | EU enforcement dates |
|---|---|--------------------------------|-----------------------------|
| <u>Medical Device Problem</u> | <ul style="list-style-type: none"> Medical device problem (Annex A) + reference mapping + Annex A in new format | April 2017 | January 2020 |
| <u>Cause Investigation</u> | <ul style="list-style-type: none"> Type of investigation (Annex B) + reference mapping + Annex B in new format Investigation findings (Annex C) + reference mapping + Annex C in new format Investigation conclusion (Annex D) + reference mapping + Annex D in new format | October 2017 | January 2020 |
| <u>Health Effects</u> | <ul style="list-style-type: none"> Clinical signs, symptoms, and conditions (Annex E) + Annex E in new format Health impact (Annex F) + Annex F in new format | May 2019 | June 2020 |
| <u>Component</u> | <ul style="list-style-type: none"> Components and parts (Annex G in new format only) | April 2020 | May 2021 |

N.B. Depending on the status of the MIR form (e.g. initial report), operators may not have to report cause investigation (since when reporting the incident 2 weeks after its occurrence, the cause investigation may not be clear yet). However, in the “final report” of the MIR (when concluding on the incident), Annexes B, C, D terms have to be used as well (even if the investigation was inconclusive – there are relevant terms).

² The IMDRF website does not provide the correct dates of publication of the Annexes. The date of publication on IMDRF relates to the guidance document, that means that whenever there is a change in the guidance the date is updated.

2. Changes occurred in Edition 4 of IMDRF website

The files for the IMDRF codes edition 4 currently available at the IMDRF website are not machine readable. The principal changes that have been included relate mainly to the formatting and the layout. The files relating to the different annexes have been harmonized and new columns have been added. These include a column on "status" providing information on whether the term is active or not. The 'status' column will provide traceable information regarding the totality of active terms and will allow users to track the development of changes over time.- This should support the accuracy of term use by stakeholders. The status will equally be displayed in the web browser of the terminology (see section 3).

The representation of the hierarchical structure has also been changed. With the new layout it is much easier to produce machine readable files (e.g. csv) as compared to the previous format. JSON files have been created but they are currently used only by the browser.

The new status columns in the sheets and in the browser highlight any modifications to terms. Additionally, a standardized and simple change log (in excel) has been prepared for the maintenance phase which will summarize the results of any revision and will be publicly available.

3. IMDRF Web browser

These IMDRF adverse event terminologies are new for both EU and 3rd country operators which have no or little experience in using these new terminologies. At the same time, many operators have been using their own internal coding systems or in some cases they have experience of other national (e.g. FDA codes) or international nomenclatures (e.g. MedDra).

To comply with these timelines outlined in Table 1, manufacturers need to map their internal company codes to the IMDRF adverse event codes. To assist in this process, the IMDRF WG has developed and endorsed a web-based browser which maps either internal codes, MedDra codes with the IMDRF codes and helps to select the correct ones.

The IMDRF terminology web browser is available online at:

<http://www.imdrf.org/workitems/wi-aet.asp>

C. Supporting documents for implementation

The main tool to support the implementation of the MIR form is the **helptext document**. It indicates **which fields are mandatory/voluntary** in regard to different types of reports (initial, update, final etc.) corresponding to the main reporting stages. It also contains **practical guidance on how to fill certain fields** (description of the fields). The help text is a living document as additional clarifications will be included as they come up.

D. Versioning and updating of the MIR form

Since its first publication in December 2018, the MIR form has been updated twice: publication of MIR version 7.1 and of version 7.2 which includes minor editorial revisions (such as the selected nomenclature reference). The XSD has been updated, as well. Versioning and change log have been implemented to ensure transparency regarding the changes and have been published on the COM website.

The use of the new MIR form has been mandatory since January 2020 and as a general rule, we advise sending both the PDF and XML to national Competent Authorities as not all Member States will adopt the new XML (XSD) schema.

The updated version 7.2.1 published in May 2020 does not modify the XML structure but it addresses a number of discrepancies that were identified between the PDF and the XML files with version 7.2. It has also adjusted the free text fields so they are now auto expandable to allow a better view of the information provided and the limitation (100,000,000) for the devices on the market has been removed. A change log file is also available on the Commission website with the list of all the changes.

To ensure **not creating discrepancy between operators** which have already integrated the version 7.2 in their internal IT system, there is **a transition phase for the use of version 7.2.1 until January 2021**.

It was agreed, when the version 7.2 was endorsed by the PMSV WG, not to modify the XML structure for a significant period of time. Therefore the new a 7.3 version, with modifications of the XML structure, which is necessary for full compliance with the future Eudamed, is planned to be developed at a later stage.

E. Main IT issues

The integration of the new MIR form by manufacturers in their internal IT systems has triggered numerous IT related questions. The main topics are addressed in Annex.

ANNEX on related IT issues

1. How to unsecure the PDF version of the MIR form?

The published MIR form is password-protected so it may be necessary to unlock it for specific purposes (e.g. translating the form, implementing it into in-house IT systems).

You can request the password for specific authorised uses, which are subject to terms and conditions, at the following URL:

<https://ec.europa.eu/eusurvey/runner/mirpwdrequest>

2. How to populate the PDF version of the MIR form with an XML file?

The Acrobat software (e.g. Reader, Professional) only allows the user either to save the form content or to import an XML file in one form. For this reason, to import an XML file into the PDF version of the MIR form, it must be used the file named *MIR_form_[version]_import.pdf* in which the extended Readers functions are disabled. For the import: open this file with Acrobat Professional, click the button *Import XML* and select the XML file to be imported. Then click the button *Align form after import* to apply some validation rules. The form now can be saved with another name (*Save As*). Before importing the XML file, check that it is structured according to the schema (XSD) of the corresponding type of report (e.g. initial, follow-up, final).

3. Where is it possible to retrieve the structure of the XML generated by the MIR form?

This information is available in the five XSD files (available on the Commission website) corresponding to the types of MIR form that reflect the reporting stages:

- Initial
- Follow up
- Combined initial and final
- Final (Reportable incident)
- Final (Non-reportable incident)

The files describe the structure of the XML for each type of form. The XSD files also provide data type for each element.

4. Is it possible to automatically populate the MIR form?

Yes. There are several solutions that can be used (e.g. Java libraries) and most of them require to unsecure the PDF form. The password to do that can be requested at:

<https://ec.europa.eu/eusurvey/runner/mirpwdrequest>

The PDF form incorporates two XSL files (available on the Commission website) and they are used as follows:

- *incident_in_[version].xsl*: this transformation is applied to the XML file that is being imported (i.e. when the button Import XML is clicked, see point 1 of this document)

- *incident_out_[version].xsl*: this transformation is applied when the XML file is generated (i.e. when the button *Submit XML by Email* is clicked)

In case you intend to automate the above import and export XML functions in your information system, make sure that these transformations are properly applied and fully functional.

Once the XML is imported, it is necessary to execute the following functions embedded in the PDF form:

```
glob.checkDistribution();
glob.checkSubmitter();
glob.checkTypeReport();
glob.checkRiskClass();
glob.checkRiskAssRev();
glob.populateSummary();
glob.populateSubmitter;
glob.popShowLongTextFields();
```

5. Date fields

Some dates fields require some validation criteria that could not be embedded in the XSD files as of compatibility with XML 1. For this reason, they have been implemented in the PDF according to the following rules:

2.1.a Date of submission \geq current date

2.1.b Date of incident \leq 2.1.a Date of submission

2.1.c Manufacturer awareness date \leq 2.1.a Date of submission

2.1.c Manufacturer awareness date \geq 2.1.a Date of incident

2.1.e Date of the next report (for Initial and Follow-up reports) \geq 2.1.a Date of submission

6. Use of Partial Dates

Questions were raised whether, when the exact date is unknown, would the registration of partial dates (month / year) be allowed or the automatic attribution of the 1st day of the month by the manufacturer IT system? the manufacturer IT system database would generate: Date format: ??-Feb-2020 and the date to be Transmitted would be 2020-02-01.

There are multiple dates the manufacturer should 100% know: the date of the report, the awareness date, the date of manufacturing, etc. For these later dates a partial format would not be acceptable.

For the dates where the manufacturer under certain circumstances isn't certain (e.g. date of incident), the MIR form allows a range to be filled out: manufacturers need **to fill out a starting date of the range & ending date of the range**.

If the manufacturer's IT system automatically assigns the 1st day of month when the date is unknown, competent authorities may make the wrong interpretation that the manufacturer knows the exact date of the incident and that this incident occurred on the 1st day of the month (see example in picture 1 taking into account that the MIR automatically copies the first date in the second field as a placeholder, the manufacturer does not have to manually fill out 2 dates to indicate an incident with an exact date).

Picture 1

| | | |
|----------|------------------------------------|------------|
| b | Date of incident (e.g. 2012-10-23) | |
| | 2020-05-01 | 2020-05-01 |

When a manufacturer only knows that the incident occurred in May for example, he should fill out a possible range with 2 dates (this range can be a few days or the full month). So an incident date filled out as a range with 2 different dates (see picture 2) would be interpreted by the competent authorities as an incident date of which the manufacturer was not 100% sure and that is why he can only provide a range over which he is sure the incident occurred.

Picture 2

| | | |
|----------|------------------------------------|------------|
| b | Date of incident (e.g. 2012-10-23) | |
| | 2020-05-01 | 2020-05-31 |

The same considerations apply for the automatic generation of the XML.

7. Fields with multiple values

There are some fields that allow to list multiple values separated by a defined character (i.e. ";") as described in the HelpText. The XSL file *incident_out_[version].xsl* described in question 2 splits their content in different elements (identified with the suffix LI) in order to be imported in to Eudamed when it will be fully operational. An example is displayed below:

```
<ncaRefMultiDev>aa;bb;cc;</ncaRefMultiDev>
<ncaRefMultiDevLI>aa</ncaRefMultiDevLI>
<ncaRefMultiDevLI>bb</ncaRefMultiDevLI>
<ncaRefMultiDevLI>cc</ncaRefMultiDevLI>
```

The XML elements with this characteristic are the following:

```
incident/admin_info/ncaRefMultiDev
incident/admin_info/eudamedRefMultiDev
incident/admin_info/mfrRefMultiDev
```

incident/admin_info/ncaRefFSCA
incident/admin_info/eudamedRefFSCA
incident/admin_info/mfrRefFSCA
incident/admin_info/psrId
incident/admin_info/pmcfpmpfId
incident/device_info/nbCertNum
incident/device_info/nbCertNum2
incident/device_info/distribution/otherCountries

8. MIR signature process

Fill all relevant fields from the MIR form

Then go to General Comments section

The screenshot shows the Adobe Acrobat Reader DC interface. The main content area displays a form with the following text and fields:

representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form Save as PDF

Date

Signature/Digital Signature

Send as XML file Submit XML by Email

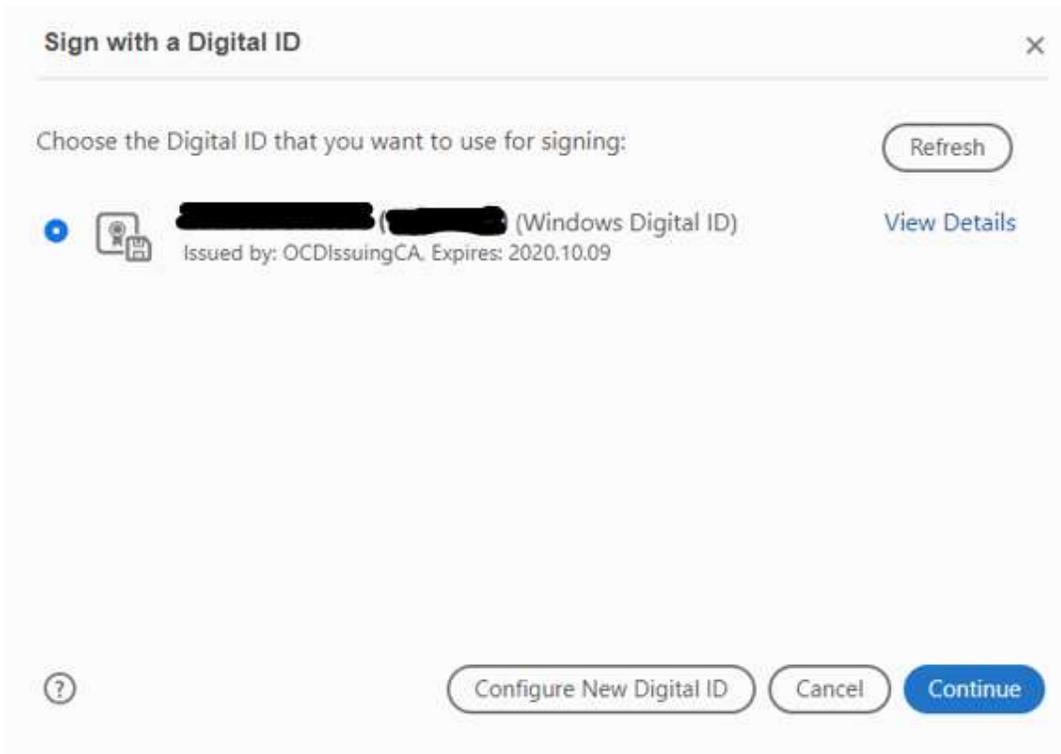
Send as PDF file Submit PDF by Email

2.6 b - Relevant associated devices used with the device being reported on

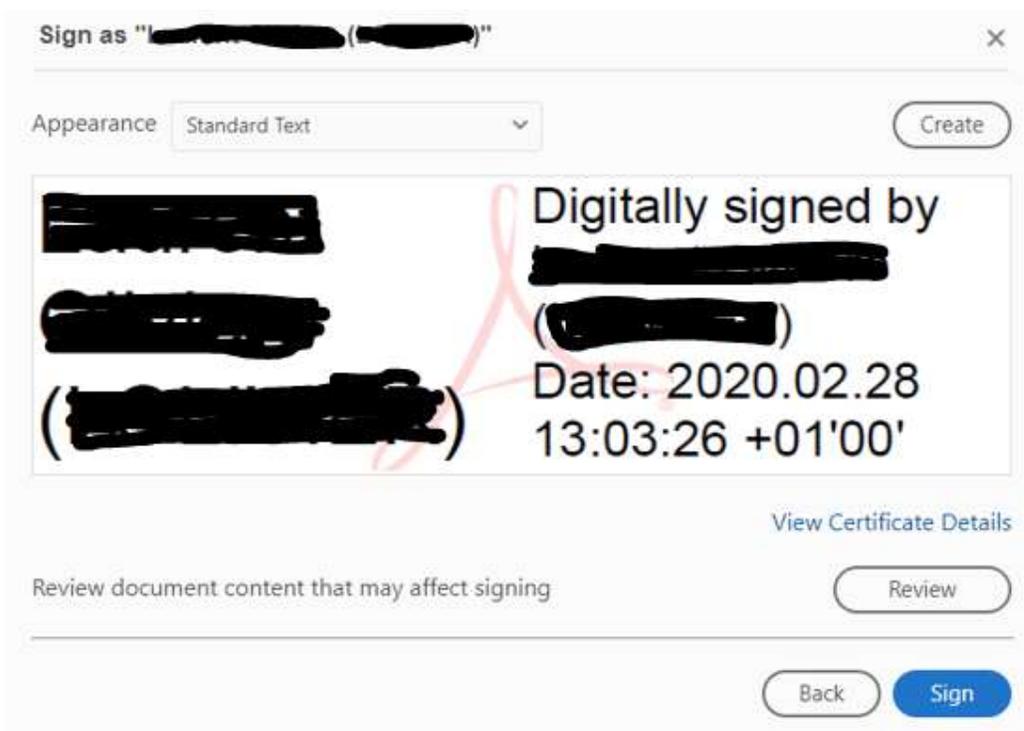
ORTHO VISION BioVue Analyser (product code 6904579; serial numbers J80002109 and J80002150), is designed to automate in vitro immuno-hematological testing of human blood utilizing Ortho BioVue System cassette technology and digital image processing.
ORTHO BioVue System ABO-Rh Reverse Grouping Cassette (product code 707155; lot ABR234A; expiry date 13 May 2018;
ORTHO BioVue System ABO-Rh Forward Grouping Cassette (product code 707155; lot ABR234A; expiry date 13 May 2018)

The right-hand side of the screenshot shows the Adobe Acrobat Reader DC toolbar with various tools like Export PDF, Create PDF, Edit PDF, Comment, Combine Files, Organize Pages, Redact, Protect, Compress PDF, Fill & Sign, Send for Review, and More Tools.

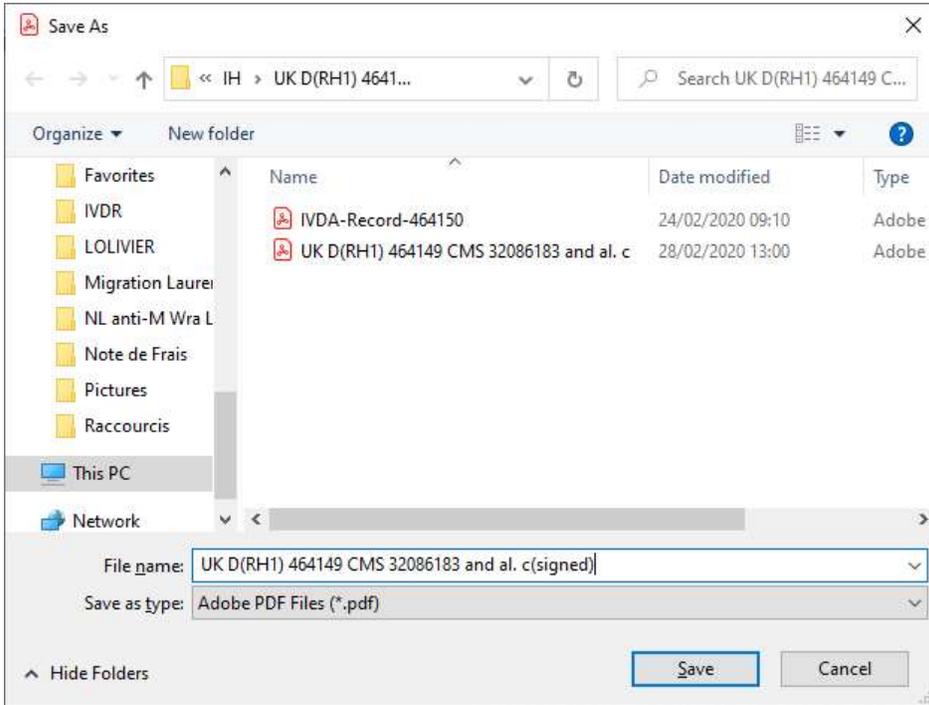
Click on *Signature/Digital Signature*



Select the correct Digital ID and click *Continue*



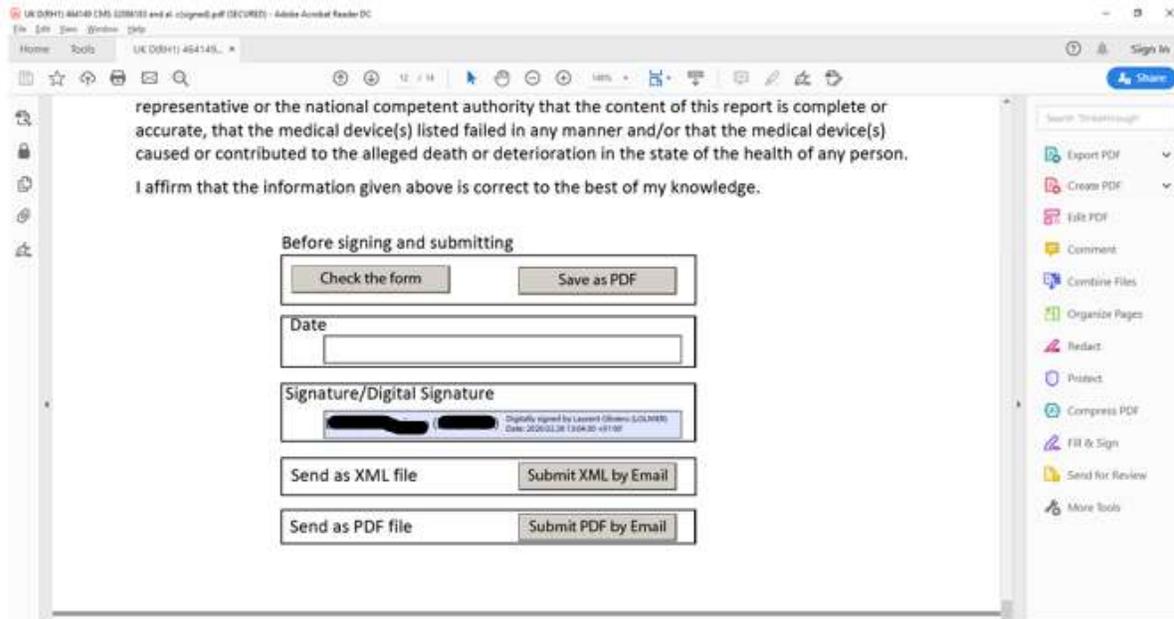
Click *Sign*



Save as ...(signed) Click Save



Enter the password then click *Allow*



Document is electronically signed but still can be edited.

9. Editing of the MIR form after signature of the MIR form

The MIR form can be edited after adding the electronic signature while editing is no longer possible once the form is signed and submitted as XML or PDF.

(Either by clicking on "Submit as XML by email" or by clicking on "Submit as PDF by email" should result in locking the form).

10. Acceptance of signed and non signed version by the national competent authorities

The national competent authorities in the EU do accept either signed or none-signed MIR forms.

They generally also accept self-signed certificates for digital signature(s), independently whether linked to an individual or to an organization/company.