

**FRENCH NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS SAFETY
 INSPECTION DIVISION**

Trials and Vigilances Inspection Department

Dossier followed by

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Réf : MV-Mentor-20102015-C3-15IPV019

FINAL INSPECTION SUMMARY REPORT

Company inspected	MENTOR MEDICAL SYSTEMS B.V Zernikedreef 2 2333 CL Leiden The Netherlands Phone : +(31) 71 751 3600
Activities	<input checked="" type="checkbox"/> Non OBL Manufacturer (Responsible for marketing in Europe) <input type="checkbox"/> OBL Manufacturer (Responsible for marketing in Europe) <input type="checkbox"/> Medical devices Assembler <input checked="" type="checkbox"/> European Representative <input type="checkbox"/> Importer <input type="checkbox"/> Distributor <input type="checkbox"/> Sub-Contractor <input type="checkbox"/> Other
Date of inspection	20 th to 22 nd October 2015.
ANSM Inspector	
Summary of the main stages of the inspection	Reference of the mission : 15IPV019. Mission letter dated 6 th October 2015. Date of shipment of the preliminary inspection report : 24 th November 2015. Dates of receipt of the responses from the Company : 21 st December 2015.

I. ASSESSEMENT OF THE RESPONSES OF THE COMPANY BY THE INSPECTOR

The findings notified by the inspector in the preliminary inspection report are recalled and summarized in this final report, preceded by a number in 'D' for the deviations and a number in 'R' for the remarks.

The assessment of the responses provided by the company is preceded by the sign « → ».

The term '*satisfactory*' means that the reported response provides evidence of the implementation of appropriate corrective and/or preventive action(s).

The term '*acceptable*' means that the reported response is appropriate in principle, but in the absence of evidence submitted, the implementation of the corrective and/or preventive action(s) could be verified during a next inspection.

The term '*noted*' means that the reported response and corrective and/or preventive action(s) need to be completed or deepened.

The term '*not satisfactory*' means that the response is not adequate to provide a solution to the reported findings.

Quality Management System (QMS)

R1 MENTOR shall update and complete its procedures regarding the management of its documentary system (procedures, records and archiving), so that they clearly mention :

1. The management of the training of all the addressees concerned by the new documents and updates of the existing documents ;
2. A period of archiving at least equivalent to that laid down by the European legislation in force (MDD Annex II point 6.1), regarding the EC Declarations of conformity, EC Certificates of the medical devices, decisions and reports from the notified body, which shall be at least :
 - 15 years after the last product has been manufactured, in the case of implantable devices ;
 - 5 years after the last product has been manufactured, for the other devices.
3. The restrictions of access to the complaints and MV documents in paper, to the only authorized staff.

→ Point 1 : Acceptable response, considering the commitments to update, by 31st March 2016, the procedure *SOP-1007* to better specify the interrelation between the different automated systems that are used as part of the training process ;

→ Point 2 : Response noted, considering the commitments to update, by 31st March 2016 :

- The procedure *100095458* to precise the retention period for '*site registrations*' to 15 years after the last product has been manufactured ;
- Update the record description to precise that '*site registrations*' include the QS certificates, EC certificates and Declarations of conformity ;

However, it is reminded that decisions and reports from the notified body shall be included among the '*site registrations*' to retain for 15 years after the last product has been manufactured.

→ Point 3 : Acceptable response, considering the commitments to update, by 31st March 2016, MENTOR Texas procedure *SOP-TX-151* to include restriction of access for paper to authorized staff only.

R2 MENTOR MEDICAL SYSTEMS B.V shall update and complete its procedures regarding the management of the skills and habilitations of its staff, insofar the documentation system does not mention the modalities of initial and periodic trainings to the risks associated to the BIs, intended to the staff involved or likely to be involved in the communications of complaints and MV cases (staff in charge of the management of complaints and MV, any other staff that may direct such communications to the staff in charge of the management of complaints and MV...).

→ Response noted, considering the commitments to :

- Develop, by March 30th 2016, training material to define requirements for all employees and stakeholders (distributors, contractors...), with regards to complaint identification, timely reporting and support of complaint investigation ;
- Deploy, by April 30th 2016, the trainings to MENTOR employees and contractors involved on complaint identification, timely reporting and support of complaint investigation, followed by annual retrainings.

However, it is reminded that MENTOR MEDICAL SYSTEMS B.V training procedures shall be updated accordingly.

D1 The processing of the MV cases, as described in the corresponding procedure used by MENTOR MEDICAL SYSTEMS B.V, is not completely compliant with the European legislation in force (MDD Annex II point 3.1) considering the findings detailed in *Annex 2* to the preliminary inspection rapport, which implies to update this procedure so that :

1. Any serious incident or risk of serious incident, whether expected/foreseeable or not, shall be reported to the concerned competent authority ;
2. Any serious incident or risk of serious incident, regardless of its likelihood of occurrence, shall be reported to the concerned competent authority (as an example, this shall apply to ALCL cases) ;
3. In case of doubt on the causality of the medical devices and thus on the reportability of an event, there should be a pre-disposition to report

→ **Not satisfactory response**, insofar the action plan provided does not mention clear commitments so that MENTOR MEDICAL SYSTEMS B.V procedures related to the MV shall be updated to include the 3 points precised in this deviation.

R3 The procedures and/or work instructions used by MENTOR MEDICAL SYSTEMS B.V in the processing of the complaints and MV cases should be completed so that they precise clearly the methodology with which the final decision of causality of the medical devices involved in the reported incidents is made and supported.

→ Acceptable response, considering the commitments to revise, by 16th February 2016, the Work Instruction *DOP-QA-4002* to document a clearly defined root cause determination methodology.

D2 The description of the MV cases processing, in MENTOR MEDICAL SYSTEMS B.V and/or MENTOR French affiliate documentation system, is not complete (MDD Annex II point 3.2, claimed ISO 13485 standard points 4.2.1 d et 4.2.2 b) insofar the documentation system :

1. Does not mention the reporting process agreed between MENTOR and ANSM regarding the BIs related incidents occurred in France, which concerns :
 - the individual cases prone to immediate notification ;
 - the clustered cases prone to periodic (yearly) notification :
 - via the *Periodic summary reports* (PSRs) ;
 - via the *Trend reports* in case of detection of drift, simultaneously to the aforesaid PSRs.
2. Does not include any procedure of preparation and submission of the PSRs to ANSM.

→ Acceptable response, considering the commitments, by 31st January 2016, to :

- Update the French local procedure *PR-FR-3-0002 'Vigilance and Field actions'* to include details on the reporting process for incidents related to BIs occurring in France ;
- Include in this SOP the table '*Critères de déclaration des incidents PMI par les fabricants*' ;
- Create a Work instruction to explain the process to prepare and submit PSRs to ANSM.

R4 The description of the *corrective and preventive actions (CAPAs/FSCAs)* management, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be completed so that it mentions provisions regarding the communications to the notified body of the *CAPAs/FSCAs* :

- Implemented on medical devices design and/or manufacturing processes and/or labelling, further to each serious incident (to prevent its recurrence) (Meddev 2.12/1 point 5.4.4) ;
- Likely to induce substantial changes to all the medical devices concerned, not only on class III medical devices (MDD Annex II point 3.4).

→ **Not satisfactory response**, insofar the action plan provided does not mention clear commitments so that MENTOR MEDICAL SYSTEMS B.V procedures include provisions regarding the communications to the notified body of the *CAPAs/FSCAs* :

- Implemented on medical devices design and/or manufacturing processes and/or labelling, further to each serious incident ;
- Likely to induce substantial changes to all the medical devices concerned.

R5 The product recall process description, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be clarified and completed, at least regarding the medical devices marketed in France, so that it :

1. Mentions that any medical device recall motivated by a technical or medical reason related to a serious incident shall be reported immediately to the European competent authorities on the territory of which the recall is to be conducted (MDD Annex II item 3.1) or that any message intended to the concerned competent authorities and to the patients and/or users, within the framework of such a situation, should be communicated in advance (48 h for example) to the concerned competent authorities ;
2. Precises the reconciliation intended to document the efficiency of the recall, with a systematic recall full balance sheet recapitulating the quantities of product units :
 - produced and/or in production ;
 - present in stocks ;
 - likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ;
 - marketed and recallable (unused) ;
 - marketed and not recallable (used).
3. Plans the evaluation of the efficiency of the recall process by simulations of recall involving the distribution stakeholders until the final clients.

→ Point 1 : **Not satisfactory response**, insofar the action plan provided is limited to mention the update of the procedure *PR-0000109 'to include time requirements for reporting'* and does not mention clear commitments regarding the product recall process description, in MENTOR MEDICAL SYSTEMS B.V documentation system, so that it mentions that any medical device recall motivated by a technical or medical reason related to a serious incident shall be reported immediately to the European competent authorities on the territory of which the recall is to be conducted or that any message intended to the concerned competent authorities and to the patients and/or users, within the framework of such a situation, should be communicated in advance (48 h for example) to the concerned competent authorities.

→ Point 2 : **Not satisfactory response**, insofar the action plan provided is limited to mention the update of the procedure *PR-0000109 'to include effectiveness check criteria'* and does not describe what are those *effectiveness check criteria'* regarding product recall.

→ Point 3 : **Not satisfactory response**, insofar the action plan provided is limited to mention the update of the procedure *PR-0000109 'to include simulations when there has been a significant elapsed time in conducting a field action'* and does not describe what is considered as *'significant elapsed time in conducting a field action'*.

- R6 The Post Market Surveillance (PMS) process described in MENTOR documentation system and related to experience gained from devices in the post-production phase should be completed, so that it lays down provisions related to the construction and update of a consolidated survey report for each category of BIs since their first marketing, with a presentation of :
1. The incidents outcomes broken down by :
 - Typologies of incidents ;
 - Regions of occurrence of the incidents (Worldwide / Europe / local countries) ;
 - Years of occurrence ;
 - Years of sales and/or implantation ;
 - Sales volumes or numbers of BIs implanted per year (in order to assess the significance of the reported cases) ;
 - Surface (smooth or textured) of the BIs (in order to allow the inter-comparison of the Benefit/Risk ratio of the textured BIs versus smooth BIs) ;
 2. An exhaustive list of the typologies of reported incidents, from the most frequent to the rarest ones ;
 3. A methodology of identification of the key points, issues and stakes stemming from these data.
- Point 1 : **Not satisfactory response**, insofar the action plan provided does not provide commitments to update the PMS procedure so that it lays down provisions related to a presentation of the incidents outcomes broken down by :
- Years of occurrence ;
 - Years of sales and/or implantation ;
 - Sales volumes or numbers of BIs implanted per year.
- Point 2 : Acceptable response, considering the commitments to update, by 31st March 2016, the PMS procedure and related templates so that they lay down provisions related to additional analysis regarding each of the complaint typologies, including the most frequent to the rarest ones.
- Point 3 : **Not satisfactory response**, insofar the action plan provided does not provide commitments to update the PMS procedure so that it lays down provisions related to a methodology of identification of the key points, issues and stakes stemming from the PMS data.

Organization of the staff involved or likely to be involved in MV

- R7 MENTOR LLC and MENTOR MEDICAL SYSTEMS B.V should complete the job descriptions and the documentation related to the delegations of its staff, insofar :
1. The delegation form related to activities under the responsibility of the Head of the *Product Evaluation Department* is not signed by the delegates themselves, which does not certify that they know and accept these delegations ;
 2. The job description of MENTOR MEDICAL SYSTEMS B.V Plant Quality Assurance Manager does not mention his activities related to complaints and MV.
- Point 1 : **Not satisfactory response**, insofar the action plan provided does not provide clear commitments so that the delegation form related to activities under the responsibility of the Head of the *Product Evaluation Department* shall be signed by the delegates themselves.
- Point 2 : Response noted, considering the commitments to update, by 31st January 2016, the Plant Quality Assurance Manager job description (*PD-0108*) '*regarding complaint process*'. It is reminded that this update shall also include the activity related to MV.
- D3 The continuity of the MV activity within MENTOR organization is not enough documented, which induces a risk that MV cases may not all be processed and reported with the required due diligence (MDD Annex II items 3.1 and 3.2 b), in the absence of records demonstrating the continuous presence of the *Product Evaluation Department* Head's or of his delegates.
- **Not satisfactory response**, insofar the action plan provided does not provide commitments to implement records demonstrating the continuous presence of the *Product Evaluation Department* Head's or of his delegates.

Audits

R8 MENTOR should complete the audits covering its complaints and MV management, so that their scope cover the assessment of the quality and timeliness of :

- the MV serious incidents communications to the concerned European competent authorities (which would notably reduce the risk of non-compliances such as point 1 of the Major Deviation D4 mentioned in this inspection report) ;
- the responses to the requests of the competent authorities.

→ **Not satisfactory response**, insofar the action plan provided :

- Is limited to mention :
 - *'Update of procedure 100369706 Work instruction for the internal audit process – Mentor Leiden only to include guidance on how to conduct an internal audit on Materiovigilance process'* ;
 - *'Training the internal auditors on the new revision of procedure 100369706'* ;
- Does not therefore provide clear commitments so that the scope of the next audits related to the complaints and MV management activities shall cover, from now on, the assessment of the quality and timeliness of :
 - the MV serious incidents communications to the concerned European competent authorities ;
 - the responses to the requests of the competent authorities.

Management reviews

R9 MENTOR MEDICAL SYSTEMS B.V's management reviews should be completed in order to :

1. Cover the assessment of the quality and timeliness of :

- the MV serious incidents communications to the concerned European competent authorities (which would notably reduce the risk of non-compliances such as point 1 of the Major Deviation D4 mentioned in this inspection report) ;
- the responses to the requests of the competent authorities.

2. Develop the key points, issues and stakes stemming from the PMS data regarding the question of ALCLs related to BIs (see also R12 in this inspection report).

→ Response noted :

- Considering the commitments, by 31st March 2016, to *'perform more in depth analysis of the PMS and incident reporting in the future management reviews to include :*
 - a) *The MV serious incidents communications to the concerned European competent authorities ;*
 - b) *The responses to the requests of the competent authorities ;*
 - c) *Key points, issues and stakes stemming from the PMS data regarding the question of ALCLs related to BIs'.*
- Despite the documents supporting the Investigation chapter of the response file, which states that *'Previous management reviews have been checked to verify if Health authorities reporting timeliness and PMS data have been presented (meeting 29Jul15, 22Jan15, 15Jul14). All management reviews have included the health authority reporting timeliness and PMS data'*, are not provided in the response file.

Complaints and materiovigilance (MV) management

D4 Major

The management of the individual complaints and MV cases by MENTOR is not satisfactory, which compromises the proper processing and notification of the serious incidents occurred in France to ANSM, (MDD Annex II item 3.1, claimed ISO 13485 standard items 7.2.3, 8.4 and 8.5, Meddev 2.12/1 points 5.1.7 and 5.3), insofar :

1. MENTOR reported an MV case of silicone granuloma to ANSM more than 8 months after its reception by the French affiliate, whereas silicone granulomas correspond to serious incidents prone to immediate notification (Annex 3 point 2 of the preliminary inspection report) ;
2. The evaluation of the ALCL cases is limited to the analysis of the medical and scientific literature which states that risks of ALCLs on patients bearing BIs are not to be excluded, without further investigations (Annex 3 point 1 of the preliminary inspection report) ;
3. The production batch records (*DHR*) are not systematically reviewed and challenged in the processing of the complaints and MV cases, particularly when these cases refer to known and anticipated incidents, which excludes any assessment of the production impacts Annex 3 points 1, 4, 6 of the preliminary inspection report) ;
4. TRACKWISE™ database does not provide the traceability of :
 - the source documents attesting the actual dates of receipts of the complaints and MV cases communicated to MENTOR staff, with the notifiers details ;
 - the documents attesting the reporting of the serious incidents to the concerned competent authorities ;
 - requests and/or reminders which should be addressed to the notifiers in order to collect information on the complaints and MV cases, which may jeopardize the proper evaluation of the incidents gravity and of the causality of the BIs involved (Annex 3 point 3 of the preliminary inspection report).
5. TRACKWISE™ database decision tree may be empty of any information (Annex 3 point 9 of the preliminary inspection report) or may refer to decisions which are not consistent with the European legislation and guidelines in force regarding the gravity and the reportability of some MV cases, insofar silicone granulomas and surgical interventions related to explantations, which are serious incidents prone to immediate notification, are not ranked as such in this database, which may jeopardize the reporting of the serious incidents with the required due diligence to the concerned European competent authorities (Annex 3 points 5, 7 of the preliminary inspection report).

→ Acceptable response, considering the commitments to :

- Update, by 30th March 2016, *SOP-TX-113* (MV procedure), Regulatory Agency reporting and related procedures to :
 - predispose MENTOR to report in cases where information is unclear or absent ;
 - include provisions for documenting consultation with a qualified clinician in cases where information is unclear or absent ;
- Update, by 30th March 2016, the local French procedure *PR-FR-3-0002* accordingly ;
- Train the employees involved in this process revision, including local affiliates, by 30th April 2016 ;
- Perform, by 29th January 2016, an evaluation on form 100220996 '*Registre des réclamations*', from 2010 to 2015, to verify if there are other cases which have not been reported and report these cases to ANSM if applicable ;
- Update *DOP-QA-4002*, Processing of a complaint file and investigation guidelines, by 29th February 2016, to require *DHR* review in all MV cases ;
- Train the employees involved in this *DOP-QA-4002* process revision, by 15th March 2016 ;
- Implement a new global complaint database to replace TRACKWISE in US and France, by 31st July 2016.

R10 MENTOR should implement :

1. Appropriate actions so that its complaints and MV management database includes fields that shall summarize the information and the evaluations made with regards to each key point of the processing of each case, with the attached supporting documents or references, concerning :
 - The *date and mode of reception of the source document* related to the case notification to MENTOR (letter, fax, e-mail, report of phone call...), with the identification of the notifier and MENTOR staff addressee ;
 - The *gravity* of the case (serious / non serious) ;
 - The *causality* of the medical device(s) involved (established, possible, excluded or unknown) ;
 - The *risk(s)* related to the patient ;
 - Potentialities of *use error* ;
 - Potentialities of *misuse* ;
 - The *reportability* of the incident to the concerned competent authorities ;
 - The *reference of the notification of the incident* (is serious) to the concerned competent authorities ;
 - The *final evaluation, conclusion and decision* related to the case ;
 - The *criteria triggering the closure of the case*.
2. A quality control of the data entered in this database.

→ Response noted, considering the commitments to implement a new global complaint database to replace TRACKWISE in US and France, by 31st July 2016. This new database should include fields related to the items quoted in R10.

Product recall

R11 MENTOR MEDICAL SYSTEMS B.V should assess the efficiency of its recall process and the proactivity of its partners (customers and distributors) in this matter by conducting periodic recall simulations, documented with :

1. Reconciliations that shall summarize the quantities of product units :
 - produced and/or in production ;
 - present in stocks ;
 - likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ;
 - marketed and recallable (unused) ;
 - marketed and not recallable (used).
2. Conclusions and potential areas of improvements that may be deemed necessary, following such simulations.

→ **Not satisfactory response**, insofar the action plan provided is limited to mention :

- The update of the procedure *PR-0000109* :
 - '*To include effectiveness check criteria*' and does not describe what are those *effectiveness check criteria*' regarding product recall ;
 - '*To include simulations when there has been a significant elapsed time in conducting a field action*' and does not describe what is considered as '*significant elapsed time in conducting a field action*' ;
- The training of the people who are involved on this new revision.

Systematic review of experience gained from devices in the post-production phase (PMS)

R12 MENTOR should complete its BIs post-market survey, so that the PMS reports present :

1. An analysis of the incidents outcomes broken down by BI surfaces (smooth and textured), in order to allow the inter-comparison of the Benefit/Risk ratio of the textured BIs versus smooth BIs ;
2. An exhaustive list of the typologies of reported incidents, from the most frequent to the rarest ones ;
3. An in depth analysis of the key points, issues and stakes stemming from the data related to ALCL cases, including the demonstration of the preservation of the BIs' Benefit/Risk ratio.

- Point 1 : Acceptable response, considering the commitments to update, by 29th July 2016, the PMS reports related to BIs so that they include :
 - Details on surface type (smooth or textured) as it relates to complaint rates ;
 - Comments regarding the acceptability of smooth versus textured surface ;
 - Independent benefit/risk assessment.
- Point 2 : Acceptable response, considering the commitments to update, by 31st March 2016, the PMS procedure and related templates so that they lay down provisions related to additional analysis regarding each of the complaint typologies, including the most frequent to the rarest ones.
- Point 3 : **Not satisfactory response**, insofar the action plan provided does not provide commitments so that the PMS reports present an in depth analysis of the key points, issues and stakes stemming from the data related to ALCL cases, including the demonstration of the preservation of the BIs' benefit/risk ratio.

II. FINAL CONCLUSION

The inspection carried out from 20th to 22nd October 2015 at MENTOR MEDICAL SYSTEMS B.V site located Zernikedreef 2, 2333 CL, Leiden, The Netherlands, allowed to collect the information related to the organization and to the activity of this company regarding materiovigilance.

As a result of this mission, the following findings raised in the preliminary inspection report did not receive satisfactory responses :

Quality Management System (QMS)	
D1	<p>The processing of the MV cases, as described in the corresponding procedure used by MENTOR MEDICAL SYSTEMS B.V, is not completely compliant with the European legislation in force (MDD Annex II point 3.1), which implies to update this procedure so that :</p> <ol style="list-style-type: none"> 1. Any serious incident or risk of serious incident, whether expected/foreseeable or not, shall be reported to the concerned competent authority ; 2. Any serious incident or risk of serious incident, regardless of its likelihood of occurrence, shall be reported to the concerned competent authority (as an example, this shall apply to ALCL cases) ; 3. In case of doubt on the causality of the medical devices and thus on the reportability of an event, there should be a pre-disposition to report.
R4	<p>The description of the <i>corrective and preventive actions (CAPAs/FSCAs)</i> management, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be completed so that it mentions provisions regarding the communications to the notified body of the CAPAs/FSCAs :</p> <ul style="list-style-type: none"> • Implemented on medical devices design and/or manufacturing processes and/or labelling, further to each serious incident (to prevent its recurrence) (Meddev 2.12/1 point 5.4.4) ; • Likely to induce substantial changes to all the medical devices concerned, not only on class III medical devices (MDD Annex II point 3.4).
R5	<p>The product recall process description, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be clarified and completed, at least regarding the medical devices marketed in France, so that it :</p> <ol style="list-style-type: none"> 1. Mentions that any medical device recall motivated by a technical or medical reason related to a serious incident shall be reported <u>immediately</u> to the European competent authorities on the territory of which the recall is to be conducted (MDD Annex II item 3.1) <u>or</u> that any message intended to the concerned competent authorities and to the patients and/or users, within the framework of such a situation, should be communicated in advance (48 h for example) to the concerned competent authorities ; 2. Precisely the reconciliation intended to document the efficiency of the recall, with a systematic recall full balance sheet recapitulating the quantities of product units : <ul style="list-style-type: none"> • produced and/or in production ; • present in stocks ; • likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ; • marketed and recallable (unused) ; • marketed and not recallable (used). 3. Plans the evaluation of the efficiency of the recall process by simulations of recall involving the distribution stakeholders until the final clients.
R6	<p>The Post Market Surveillance (PMS) process described in MENTOR documentation system and related to experience gained from devices in the post-production phase should be completed, so that it lays down provisions related to the construction and update of a consolidated survey report for each category of BIs since their first marketing, with a presentation of :</p> <ol style="list-style-type: none"> 1. The incidents outcomes broken down by : <ul style="list-style-type: none"> • Years of occurrence ; • Years of sales and/or implantation ; • Sales volumes or numbers of BIs implanted per year. 2. A methodology of identification of the key points, issues and stakes stemming from these data.

Organization of the staff involved or likely to be involved in MV	
R7	MENTOR LLC and MENTOR MEDICAL SYSTEMS B.V should complete the documentation related to the delegations of its staff, insofar the delegation form related to activities under the responsibility of the Head of the <i>Product Evaluation Department</i> is not signed by the delegates themselves, which does not certify that they know and accept these delegations.
D3	The continuity of the MV activity within MENTOR organization is not enough documented, which induces a risk that MV cases may not all be processed and reported with the required due diligence (MDD Annex II items 3.1 and 3.2 b), in the absence of records demonstrating the continuous presence of the <i>Product Evaluation Department</i> Head's or of his delegates.
Audits	
R8	MENTOR should complete the audits covering its complaints and MV management, so that their scope cover the assessment of the quality and timeliness of : <ul style="list-style-type: none"> • the MV serious incidents communications to the concerned European competent authorities ; • the responses to the requests of the competent authorities.
Product recall	
R11	MENTOR MEDICAL SYSTEMS B.V should assess the efficiency of its recall process and the proactivity of its partners (customers and distributors) in this matter by conducting periodic recall simulations, documented with : <ol style="list-style-type: none"> 1. Reconciliations that shall summarize the quantities of product units : <ul style="list-style-type: none"> • produced and/or in production ; • present in stocks ; • likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ; • marketed and recallable (unused) ; • marketed and not recallable (used). 2. Conclusions and potential areas of improvements that may be deemed necessary, following such simulations.
Systematic review of experience gained from devices in the post-production phase (PMS)	
R12	MENTOR should complete its BIs post-market survey, so that the PMS reports present an in depth analysis of the key points, issues and stakes stemming from the data related to ALCL cases, including the demonstration of the preservation of the BIs' benefit/risk ratio.

Consequently, the corrective and preventive actions proposed in response to the preliminary inspection report are not likely to reduce all the identified risks, which does not allow this company to be able to keep under control its materiovigilance activities, in compliance with the applicable regulations.

Further corrective and preventive actions should be taken as soon as possible.

Saint-Denis, 28th December 2015.

ANSM Inspector