THE MINISTRY OF HEALTH

2692

Pursuant to Article 64, paragraph 2 of the Medical devices Act (Official Gazette 76/2013), the Minister of Health hereby issues the

ORDINANCE

ON MONITORING ADVERSE INCIDENTS RELATED TO MEDICAL DEVICES

I. GENERAL PROVISIONS

Article 1

This Ordinance lays down the system of reporting and assessment of adverse incidents and safety corrective measures related to medical devices, which means the system of medical devices vigilance and activities that should be undertaken by manufacturer, manufacturer's authorised representative or the Agency for Medicinal Products and Medical Devices (hereinafter: Agency) when it receives an information on adverse incident related to medical devices.

Article 2

1) The main purpose of the medical devices vigilance system is to improve the health and safety of patients, users and other persons in order to reduce the probability of adverse incidents recurrence
2) The provisions of this Ordinance apply to medical devices that.
   – are CE marked,
   - are not CE marked but fall under the scope of the Medical Devices Act (hereinafter: Act), i.e. custom made medical devices ,
   - are not CE marked hence they are on the market prior to the entry into force of the Act.
3) The provisions of this ordinance that apply to medical devices manufacturers apply also to authorised manufacturer representatives.

Article 3

Included in the vigilance system are:

- medical devices manufacturers and authorised manufacturer representatives,
- importers and wholesalers,
- the Agency,
- notified bodies for conformity assessment
- patients, users and other persons coming in contact with medical devices,
- the European Commission.

Article 4

For the purpose of this Ordinance, the following terms shall bear the following meanings:

1. Abnormal use is an act or omission of an act by the operator of user of a medical device as a result of conduct which is beyond the intended use of the medical device.
2. Corrective action is an action that eliminates the cause(s) of potential nonconformities, or other undesirable situations and is taken to prevent occurrence
3. Field safety corrective action is an action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health which may be associated with the use of a medical device that is placed on the market and may include :
   - medical device recall;
   - medical device modification;
   - medical device exchange;
   - medical device destruction;
   - retrofit by purchaser of manufacturer's modification ore design change
   - advice regarding the use of the device

The manufacturer informs the medical device users from this paragraph via Field safety notice in the Annex III of this Ordinance and it is its integral part.

4. Modification of medical device may encompass the following:
   - permanent or temporary changes to labelling or instructions for use
   - software upgrades including those carried out long distance
   - changes to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the medical device.
   - advice relating to a change in the way the device is used.
5. Field safety notice is communication to customers and/or users sent out by a manufacturer in relation to a Field corrective action.
6. Harm is a physical injury or damage to the health of people, or damage to property or the environment.
7. Immediately means without any delay that could not be justified.
8. Indirect harm – diagnostic medical devices that do not act directly to individuals, all "in vitro" diagnostic medical devices and medical devices for "in vitro" fertilisation and assisted fertilisation, may cause injuries that may be the result of a medical decision, action(s) taken based on the results obtained my means of a medical device or consequence of an inappropriate treatment of cells or organs outside of the human body that will later be transferred to a patient, i.e. misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment , inappropriate transfusion. For self-testing devices, a medical decision may be made by the user of the device who is also the patient.
9. Operator is a person handling equipment.
10. Periodic summary reporting is an alternative reporting regime that is agreed between the manufacturer and the Agency for reporting similar incidents with the same device or device type in a consolidated way where the root cause is known or an Field safety corrective action has been implemented
11. Serious public health threat is any event type which results in imminent risk of death, serious deterioration in state of health , or serious illness that requires prompt remedial action which includes: events that are of significant and unexpected nature such that they become alarming as a potential public health hazard , the possibility of multiple deaths occurring at short intervals. These events may be identified by the Agency or by the manufacturer.

12. Trend reporting is a reporting type used by the manufacturer when a significant increase in events not normally considered to be incidents and for which pre-defined trigger levels are used to determine the threshold for reporting.
13. Unanticipated deterioration in state of health is considered unanticipated if the condition leading to the event was not considered in a risk analysis.
14. Use error is an act or omission of an act , that has a different result to that intended by the manufacturer or expected by the operator of the medical device.
15. User is a health care institution, professional, carer or patient using or maintaining medical devices.

II MANUFACTURERS' ROLE

Article 5

1) The manufacturer is required
   - after finding out about an event and that one of his medical devices may have caused or is involved to this event, to determine whether it is an adverse incident that should be reported
   - when the reporting criteria are fulfilled, to report to the Agency for recording and evaluation, the adverse incident regardless whether is it a direct or indirect injury or situation in which an injury may occur, if the same event reoccurs, as well as Field safety corrective measures; no information should be unnecessary delayed, if the reason is an incomplete information.
   - carry out investigation about adverse incidents and undertake necessary corrective actions.
   - submit the final report at the end of investigation of every reported adverse incident, unless the initial and the final report are combined in one report. But not every incident report will lead to a corrective action.
   - keep files of all adverse incidents and Field safety corrective actions, including those adverse incidents that do not fulfil the criteria for reporting,
   - take care that all involved in the process of placing medical devices on the market (i.e. wholesalers) are permanently informed about adverse incidents and field safety corrective actions,
   - report to the Agency the Field safety corrective action related to adverse incidents which occurred outside the Republic of Croatia , let to a Field safety corrective action relevant to the territory of the Republic of Croatia,
   - inform users about the Field safety corrective action via Field safety notice,
   - provide the notified body for conformity assessment with information about all relevant changes derived from vigilance systems if they impact the medical device conformity,
   - regularly update details about persons responsible for vigilance as well as other changes that may impact the vigilance system,
   - submit a report to the Agency when the adverse incident occurred through a combined use of two or more separate medical devices (and/or accessories) manufactured by different manufacturers, every manufacturer should separately submit the report to the Agency.
2) The adverse incident reporting to the Agency is not considered acceptance of responsibility for adverse incident and its consequences.

Article 6

1) Adverse incident is every incident that fulfils the following reporting criteria:

1. Event

a) defect, malfunction, deterioration of characteristics or performance, in general a failure to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.
b) false positive or false negative test results that may lead to life-threatening situations or fall outside the declared performance of the test,
c) unanticipated adverse reactions or unanticipated side effects
d) interactions with other substances or products
e) degradation/destruction of the device
f) inappropriate therapy,
g) an inaccuracy in the labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies.,
h) other events and situations when product testing, testing of information gathered by means of the product, or any other scientific information indicating the factor that may lead or may have led to an event

2) The medical device is suspected to be a contributory cause of the incident, taken into account:
   - the opinion, based on available evidence, of healthcare professionals,
   - the results of the manufacturer's own preliminary assessment of the incident,
   - evidence of previous, similar incidents,
   - other evidence
   - in complex situations, the manufacturer should assume that the device may have caused or contributed to the incident and should undertake precautionary measures

2. The event may lead to one of the following outcomes:
   - death of a patient, user or other person
   - serious deterioration in state of health of a patient, user or other person.

3) A serious deterioration in state of health under Article 1, sub-paragraph 3 of this article includes among others and:
   a) life-threatening illness,
   b) permanent impairment of a body function or permanent damage to a body structure,
   c) a condition necessitating medical or surgical intervention to prevent life-threatening or further impairment of body functions or permanent damage to a body function,
   d) any indirect harm as a consequence of an incorrect diagnostic or "in vitro" diagnostic test when used within manufacturer's instructions for use,
   e) foetal distress, foetal death or any congenital abnormality or birth defects.

Article 7

1) The Agency may accept from a manufacturer periodic summary or trend reports , after one or more initial reports have been issued and evaluated by the manufacturer and the Agency.
2) The manufacturer and the Agency should agree on the format and frequency for certain types of device and incident.

Article 8

1) Periodic safety reporting or trend reporting is acceptable in the following cases:
1. when the manufacturer issued a Field safety notice and concluded a Field safety corrective action.
2. in case of common and well-documented incidents (identified as such in the risk analysis of the device which have already led to incident reports assessed by the manufacturer and the

Agency) in agreement with the Agency determine the way and moment to initiate the procedure.

2) Periodic summary report is to be submitted on the application form from the Annex IV which is published with this Ordinance and makes its integral part.

Article 9

1) Adverse incidents that should not necessary be reported are:

1. deficiencies of devices that are always detected by the user (that could not go undetected) prior to its use, regardless of the existence of provisions in the instructions for use.
   This is without prejudice to the fact that the user should inform the manufacturer of any such deficiency,
2. the main cause of the event is the patient condition. It is possible that the condition appeared before or during the use of a medical device. In order to justify the absence of the reporting, the manufacturer must possess the information allowing to conclude that the medical device performed as expected and that its use did not contribute or caused patient's death or seriously deteriorated his stet of health,
3. when the only cause for the event was that the device exceeded its service life or shelf-life,
4. events which did not lead to serious deterioration in state of health or death, or put the patient at risk, because a design feature protected against a fault becoming a hazard. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.
5. expected and foreseeable adverse incidents, if they are:
   - clearly identified in the labelling;
   - clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended;
   - documented in the device master record, with an appropriate risk assessment;
   - clinically acceptable in terms of the individual patient benefit,
6. adverse events that may lead to death or serious deterioration in state of health, whose risk has been quantified and found to be negligibly small. Nevertheless, if the adverse incident has led to death or serious deterioration in state of health it should be reported and reassess the risk. If reassessment determines that the risk remains negligible small previous incidents of the same type do not need to be reported retrospectively. These decisions should be justified. Changes in the trend, usually an increase, of these non-serious outcomes must be reported.

2) When making a decision about adverse incident reporting in cases from the paragraph 1, sub-paragraph 2 and 5 of this Article, the manufacturer should take account of a clinical expert opinion with regard to stipulated criteria.

Article 10

1) On identifying a significant increase or trend of events or incidents under Article 9 of this Ordinance, the manufacturer is obliged to make a written report to the Agency.
2) A written trend report should be made to the Agency, if there is a significant increase in the rate of:
   - already reportable adverse incidents
   - incidents under Article 9 of this Ordinance
   - events that are usually not reportable
3) A form for trend reporting is provided in Annex V. which makes part of this Ordinance.

Article 11

1) The manufacturer is obliged to report to the Agency all use error events that have led to death or serious deterioration in state of health or serious threat to public health.
2) Use errors under paragraph 1 of this Article should be reported to the Agency even in the case when a manufacturer:
   - notes a significant change in trend (usually an increase in frequency, or significant change in pattern of an issue that potentially may lead to death or to serious deterioration in state of health or to threat to public health),
   - initiates a corrective action to prevent death or serious deterioration in state of health or serious public health threat.
3) The manufacturer is not obliged to report use errors related to medical devices, which did not result in death or serious deterioration in state of health or serious public health threat.
4) Such events should be handled within the manufacturer's quality and risk management system.
5) A manufacturer's decision to not report the adverse incident under paragraph 3 of this Article must be justified and documented and submitted to the Agency at its request.

Article 12

The manufacturer is not obliged to report to the Agency adverse incidents resulted from abnormal use.

Article 13

1) The report of an incident should be submitted on the Application form in the Annex I. attached as integral part to this Ordinance.
2) The Application form from the Paragraph 1 of this Article serves for initial report and for follow-up and final incident report on incident.
3) If the initial report or the report from the Paragraph 1 of this Article are submitted to the Agency orally, the applicant should submit them immediately in written also.

Article 14

1) The medical device manufacturer must report incidents to the Agency in the following timescale:

1. For serious public health threat immediately, and no later than two days after awareness by the manufacturer of this threat
2. For death or unanticipated serious deterioration in state of health: immediately after the manufacturer established a link between the device and the event but not later than ten days following the date of awareness of the event.
3. Others: immediately after the manufacturer established a link between the device and the event but not later than 30 days following the date of awareness of the event.

2) If after becoming aware of ta potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer must submit a report within the timeframe required for that type of incident.

Article 15

If the manufacturer receives a user report from the Agency, he must check this report against the reporting criteria and:

- report the incident to the Agency, if the event fulfils the relevant reporting criteria or
- provide the Agency with a written justification why this is not reportable with details of what use will be made of the information if he considers the event not to fulfil the reporting criteria.

Article 16

1) The manufacturer must perform the investigation. Timeframes for follow up and/or final reports the manufacturer should define with the Agency.
2) If the manufacturer is not able to perform the investigation of an incident then he should in written inform the Agency without delay.

Article 17

A manufacturer may consult with the user on a particular incident before a report has been made to the Agency.

Article 18

1) When deciding whether the incident should be reported, the manufacturer may perform testing of medical device
2) If the manufacturer during the testing will involve altering the device in a way which may affect subsequent analysis, then the manufacturer should inform the Agency.
3) If the Agency does not inform the manufacturer 10 days following the written information from the Paragraph 2, the manufacturer may perform testing of medical device.
4) The provision of the Paragraph 2 of this Article applies to samples and any other useful information associated with the incident.

Article 19

1) The manufacturer is obliged to provide the final report to the Agency including all necessary data related to the outcome of investigation and all other undertaken measures.
2) The undertaken measures from the Paragraph 1 of this article ma include:
   - no action,
   - additional surveillance of devices in use,
   - preventive action in medical device manufacturing
   - field safety corrective action

Article 20

1) The field safety corrective action report should be submitted to the Agency before starting the field safety corrective action, on the application form given in Annex II, that is attached to this Ordinance and makes its integral part.
2) Alongside to the report from the Paragraph 1 of this article, the manufacturer is obliged to attach a field safety notice.
3) The Agency may give its comments on the field safety notice no later than 48 hours from the receiving.

4) Exceptionally to the Paragraph 3 of this Article the manufacturer is obliged to submit to the user the field safety notice if the nature of the field safety corrective action requires a shorter period
5) The manufacturer is obliged to submit the field safety notice also to the notified body that performed the conformity assessment.

Article 21

1) The manufacturer is obliged to ensure submission of the field safety notice guarantying that all users have been informed.
2) The manufacturer is obliged to submit the original of field safety notice, signed by the manufacturer's qualified person in the Croatian language.

III. THE ROLE OF THE AGENCY IN VIGILANCE SYSTEM

Article 22

In the system of medical devices vigilance the Agency:

-forwards without delay the report received from a user or another source taking account of patient's data confidentiality,

-surveys the investigation performed by manufacturer

-undertakes additional measures to those performed by manufacturer

-is obliged to inform all interested parties about the information that may contribute to prevention of further adverse incidents (or restrict their consequences) depending on the investigation outcome.

-encourages adverse incident reporting from users and other involved in placing medicinal devices on the market,

-submits at request of EU competent authorities and other national bodies responsible for medical device the information on initial or final reports on adverse incidents with obligation of keeping those data confidential,

- reviews in consultation, if possible, with manufacturer initial and final adverse incident reports and provides advise where needed and undertakes necessary measures if necessary,

-keeps record on adverse incidents and safety corrective measures.

Article 23

1) In the procedure of risk assessment of adverse incident or safety corrective action the Agency takes account of the following:
   - risk acceptability, taking account of the criteria such as causal connexion between medical device and adverse incident, technical or other cause of adverse incident, probability of problem occurrence, frequency of medical device use, possibility of adverse event identification, probability of injury, seriousness of injury, intended use of medical device and benefit of use, requirements of harmonised standards, safety aspects stipulated by legislation, potential users, affected population and other.
   - necessity of undertaking corrective action,

- appropriateness of measures that the manufacturer has already undertaken.

2) <The Agency performs the risk assessment under paragraph 1 under this Article, in collaboration with the manufacturer.

Article 24

1) The Agency surveys the investigation performed by the manufacturer and has the right to undertake additional measures in every moment, in consultations with the manufacturer, whenever possible.
2) In the investigation under paragraph 1 under this Article, the Agency surveys:
   - course (in which the investigation goes),
   - managing (how the investigation is being managed),
   - advancement (how fast is the investigation being carried out),
   - outcome (whether testing results of the medical device are satisfying).
3) The Agency may, in collaboration with pharmaceutical inspection, undertake additional actions or initiate an independent investigation if it considers necessary in consultation with the manufacturer.
4) If the Agency carries out the investigation under paragraph 3, under this Article, it is obliged to inform the manufacturer about the investigation results.

Article 25

In the procedure of investigation surveillance, the Agency may ask for additional data on the medical device, adverse incident and all other necessary data from:

- notified bodies for conformity assessment,
- users,
- other competent authorities,
- other independent bodies.

1) Within the system of medical devices vigilance the Agency follows the experience of medical devices use from different manufacturers.
2) If the Agency considers necessary, it may undertake the appropriate measures to harmonise all medical devices of the same class which may involve additional education for users, or suggestion on reclassification of medical devices and other measures.

Article 27

The Agency co-ordinates the execution of investigation, if more manufacturers are involved.

Article 28

Based on the adverse incident report of the manufacturer, the Agency may undertake the following measures:

-collection of further information,

-recommendations to manufacturer

-informing the European Commission and other competent authorities,

-consultation with notified body for conformity assessment on conformity assessment related issues,

-consultation with the European Commission in case of medical device reclassification need,

-request for further education of users or providing additional recommendations for use,

-recall of medical device and

-other measures with measures undertaken by the manufacturer.

Article 29

1) The Agency is obliged to inform the European Commission and other national competent authorities if:
a) the manufacturer is undertaking a Safety corrective action.
b) the Agency asks from the manufacturer to undertake Field safety corrective actions or introduce change(s) in the Field safety corrective action that the manufacturer has already been undertaking,
c) the manufacturer does not promptly prepare the final adverse incident report.
2) If the manufacturer undertakes corrective measures that are not important for patient safety protection or other users, the Agency is not obliged to act in accordance with paragraph 1 of this Article.

Article 30

1) The information on the on-going Field safety corrective action undertaken by the manufacturer is considered confidential, as long as the manufacturer has not made it publicly available.
2) The information under paragraph 1 under this Article will be made publicly available by the Agency, if the Agency considers it necessary for human health protection.

IV. THE ROLE OF NOTIFIED BODIES FOR CONFORMITY ASSESSMENT

Article 31

1) Notified bodies for conformity assessment undertake the following measures within the vigilance system:
   - procedure assessment from the vigilance system,
   - revision of procedure execution from the vigilance system,
   - impact assessment of procedures from the vigilance system to the issued certificate of conformity.
2) In undertaking measures under paragraph 1 under this Article, the notified bodies for conformity assessment collaborate with the Agency.

V. THE ROLE OF HEALTHCARE PROFESSIONALS

Article 32

Healthcare professionals are obliged to report adverse incidents on the Application form in the Annex VI which is attached hereto and is a part of this Ordinance.

VI. TRANSITIONAL AND FINAL PROVISIONS

Article 33

On the day of entry into force of this Ordinance, the Ordinance on adverse incidents monitoring related to medical devices ("Official Gazette", No 74/09) will be no more in force.

Article 34

This Ordinance comes into force on the eighth day from the day of its publication in the "Official Gazette".

Class: 011-02/13-02/130

Office Number: 534-10-1-2-2/4-13-1

Zagreb, 20 September 2013

Minister

Professor Rajko Ostojić, MD, PhD

m.p.

ANNEX 1 – ANNEX VI

Manufacturer's Incident Report

Application form for initial/final incident report – manufacturers

Medical device vigilance system

1. Administrative information	
Recipient: Agency for Medicinal Products and Medical Devices Address: Ksaverska cesta 4 10000 Zagreb Phone: +385 1 4884 100 (Switchboard)	
Date of this report:	
Reference number assigned by the manufacturer:	
Reference number assigned by HALMED:	
Type of report: __Initial report __Follow-up report __Combined initial and final report __Final report	
Does the incident represent a serious public health threat:	

__Yes __No	
Classification of incident: __Death __Unanticapated serious deterioration in state of health __All other reportable incidents	
Identify to what other national competent authorities this report was also sent:	
2. Information on submitter of the report	
Status of submitter: __Manufacturer __Authorised Representative __Others (identify the role):	
3. Manufacturer information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
4. Authorised Representative Information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
5. Submitter's information (if different from section 3 or 4)	
Submitter's name:	
Contact name	
Address:	
Postcode:	City:
Phone:	Fax:

E-mail	Country
6. Medical device information	
Class: __AIMD Active implants Medical device: __Class III __Class IIb __Class IIa __Class I	"In vitro" diagnostic medical device: __Annex II List A __Annex II List B __Devices for self-testing __Others
Nomenclature system (preferable GMDN):	Nomenclature code:
Nomenclature text:	
Commercial name/brand name/make:	
Model number:	Catalogue number:
Serial number:	Lot/batch number(s):
Software version number (if applicable):	
Device Manufacturing date:	Expiry date:
Implant date (for implants only):	Explant date (for implants only):
Duration of implantation (to be filled is the exact implant or explant dates are unknown):	
Accessories/associated device (if applicable):	
Notified Body (NB) ID-number:	
7. Incident information	
User facility report reference number, if applicable:	
Manufacturers awareness date:	
Date the incident occurred:	
Incident description narrative:	
Number of patients involved (if known):	Number of medical devices involved (if known):
Medical device current location/disposition (if known):	
Operator of the medical device at the time of incident (select one):	
__health care professional __patient __other	
Usage of the medical device (select from list below): __initial use	

__reuse of a reusable medical device __other (please specify) __reuse of a single use medical device or re-serviced/refurbished __problem noted prior use
8. Patient information
Patient outcome:
Remedial action taken by the healthcare facility relevant to the care of the patient:
Age of the patient at the time of incident, if applicable:
Gender, if applicable: __Female __Male
Weight in kilograms, if applicable:
9. Healthcare facility information
Name of the healthcare facility:
Contact person within the facility:
Address:

Postcode:	City:
Phone:	Fax:
E-mail:	Country:

10. Manufacturer's preliminary comments (Initial/Follow-up report)
Manufacturer's preliminary analysis:
Initial corrective actions/preventive actions implemented by the manufacturer:
Expected date of next report:
11. Results of manufacturers final investigation (Final report)
The manufacturer's device analysis results:
Remedial action/corrective action/preventive action / Field Safety Corrective Action: *NOTE: In the case of FSCA the submitter needs to fill in the appropriate form*
Time schedule for the implementation of the identified actions:
Final comments from the manufacturer:
Further investigations:
Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause ? __ Yes __ No
Number of similar incidents:
If yes, state in which countries and the report reference numbers of the incidents:

For Final Report only: The medical device has been distributed to the following countries:
Within EEA and Switzerland: ☐ AT ☐ BE ☐ BG ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GB ☐ GR ☐ HR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK ☐ TR All EEA, Candidate Countries and Switzerland Others:
12. Comments

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

::

Signature

Name City Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorised 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.

ANNEX II

REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

1. Administrative information
To which NCA(s) is this report being sent ?
Type of report: __ Initial report __ Follow up report __ Final report
Date of this report:
Reference number assigned by the manufacturer:
FSCA reference number assigned by NCA:
Incidence reference number assigned by NCA:
Name of co-ordinating national competent authority (if applicable):

2. Information on submitter of the report	
Status of submitter: __ Manufacturer __ Authorised representative __ Others	
3. Manufacturer information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
4. Authorised representative information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
5. Contact point information in the Republic of Croatia:	
Contact point name in the Republic of Croatia:	
Name of the contact person:	
Address:	
Postcode:	City
Phone:	Fax:
E-mail:	Country:
6. Medical device information	
Class:	
__ AIMD Active implants __ MDD Class III __ IVD Annex II List A __ MDD Class IIb…….…….__ IVD Annex II List B __ MDD Class IIa……..__ IVD Devices for self-testing __ MDD Class I……..__ IVD General	

Nomenclature system (preferable GMDN):	Nomenclature code:
Nomenclature text:	
Commercial name/brand name/make:	
Model number:	Catalogue number:
Serial number(s)	lot/batch number(s)
Device Manufacturing date	Expiry date
Software version number (if applicable)	
Accessories/associated device (if applicable)	
Notified body for conformity assessment:	

7. Description of Field Safety Corrective Actions

Background information and reason for the Field Safety Corrective Action:	
Description and justification of the action (corrective/preventive):	
Advice on actions to be taken by the distributor and the user:	
Progress of Field Safety Corrective Action, together with reconciliation data (Mandatory for a Final FSCA):	
Attached please find: __ Field Safety Notice (FSN) in English __ Field Safety Notice (FSN) in Croatian) __ Others (please specify)	Field Safety Notice Status: __ Draft __ Final
Time schedule for the implementation of the different actions:	
These countries within the EEA and Switzerland are affected by this Field Safety Corrective Action:	
Within EEA and Switzerland: __ AT __ BE __ BG __ CH __ CY __ CZ __ DE __ DK __ EE __ ES __ FI __ FR __ GB __ GR __ HR __ HU __ IE __ IS __ IT __ LI __ LT __ LU __ LV __ MT __ NL __ NO __ PL __ PT __ RO __ SE __ SI __ SK __ TR __ All EEA, Candidate Countries and Switzerland Others:	

8. Comments

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

……..

Signature

Name City Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

ANNEX III

FIELD SAFETY NOTICE

TEMPLATE FOR A FIELD SAFETY NOTICE

URGENT FIELD SAFETY NOTICE
(Commercial name of the affected product,
FSCA-identifier (e.g. date),
Type of action.)

Date *(date of Field Safety Notice issue)*

Attention *(please indicate the contact person)*

1. **Details on affected device(s):**

(Specific details to enable the affected product(s) to be easily identified e.g. type of device, model name and number, batch/serial numbers of affected devices and part or order number.

Insert or attach list of individual devices with a possible reference to a manufacturer web site.)

2. **Description of the problem:**

(A factual statement explaining the reasons for the Field Safety Corrective Action, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person.

Any possible risk to patients associated with previous use of medical devices.)

3. **Advise on action to be taken by the user:**

(Include as appropriate:

- *Identifying and quarantining the device,*
- *Method of recovery, disposal or modification of device*
- *Recommended patient follow up, e.g. implants, IVD*
- *Timelines*
- *Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products))*

4. **Transmission of this Field Safety Notice: (if appropriate)**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (If appropriate)

5. Contact reference person

Name, address, contact details.

The undersign confirms that this notice has been officially notified the Agency for Medicinal Products and Medical Devices.

(Closing paragraph

Signature

(NOTICE:

1. *Any comment or description intended to diminish inappropriately the risk level or to advertise or services is not appropriate for the Field Safety Notice and should be omitted.*
2. *For the purpose of records of evidence, It is recommended to include the form for receipt confirmation of Field Safety Notice.)*

ANNEX IV

PERIODIC SUMMARY REPORT

Periodic Summary Report

Medical Devices Vigilance System

1. Administrative information
Name(s) of the competent authority(s):
Date of this report:
Reference number assigned by the manufacturer:
Reference number f Field Safety Corrective Action assigned by the competent authority:
Type of report: __ Initial report __ Follow up report Follow up Number(s) __ Final report
2. Information on submitter of the report
Status of submitter: __ Manufacturer __ Authorised representative __ Others (identify the role):
3. Manufacturer information
Name of manufacturer:
Contact name of manufacturer:

Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
4. Authorised Representative Information	
Authorised representative name:	
Authorised representative contact name:	
Adress:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
5. Submitter's information (if different from section 3 or 4)	
Submitter's name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
6. Medical Device Information	
Active implantable medical device Medical device: __ Class III __ Class IIb __ Class IIa __ Class I	"In vitro" medical device: __ Annex II List A __ Annex II List B __ Devices for self-testing __ IVD general
Nomenclature system (GMDN, if available):	Nomenclature code:
Nomenclature text:	
Notified body identification number:	
Model number(s):	Catalogue number(s):
7. Periodic Summary Report Information	
PSR Type: __ Incidents described in a Field Safety Notice	__ Common and well documented incidents

If incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA:	
Stage of Periodic Summary Report based on: __ Observed Failure mode __ Root cause	
Nature of problem agreed for Periodic Summary Reporting:	

Reporting period: __ Every month __ Every 2 months __ Every 3 months __ Every 6 months __ Every 12 months

The figures in the table below rate to:	__ EEA + CH + TR	__ All National Competent Authorities indicated in Section No 1	__ Single Member State

Date of Periodic Summary report	**New incidents this period**	**Total number incidents via Periodic Summary Report**	**Total number resolved**	**Total number in progress**

8. Manufacturer's comments/investigation results

Investigation update for this period:
Initial corrective actions/preventive actions implemented by the manufacturer:
Recommended actions for this period, if any:
Expected date of next Periodic Summary Report:

9. Distribution of medical device:

Within EEA and Switzerland.

__ AT __ BE __ BG __ CH __ CY __ CZ __ DE __ DK __ EE __ ES __ FI __ FR
__ GB __ GR __ HR __ HU __ IE __ IS __ IT __ LI __ LT __ LU __ LV __MT
__ NL __ NO __ PL __ PT __ RO __ SE __ SI __ SK __ TR

All EEA, Candidate Countries and Switzerland
Others:

10. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

……

Name City Date

Annex V

Trend report

Trend report

Medical Devices Vigilance System

1. Administration Information
Recipient: Agency for Medicinal Products and Medical Devices (HALMED)
Address: Ksaverska cesta 4 10000 Zagreb
Date of this report:
Reference number assigned by the manufacturer:
Reference number assigned by HALMED:
Type of report __ Trend initial __ Trend Follow up __ Trend Final
Do these incidents/trend represent a serious public health threat ? __ Yes __ No
Identify to what other National Competent Authorities this report was **also** sent:
2. Information on the submitter of the report
Status of submitter __ Manufacturer __ Authorised Representative

__ Others (identify the role):	
3. Manufacturer information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
4. Authorised Representative information	
Name:	
Contact name:	
Address:	
Postcode:	City
Phone:	Fax:
E-mail:	Country:
5. Submitter's information (if different from section 3 or 4)	
Submitter's name:	
Contact name:	
Address:	
Postcode:	City
Phone:	Fax:
E-mail:	Country:
6. Medical Device Information	
Class __ Active implantable medical device Medical device: __ Class III __ Class IIb __ Class IIa __ Class I	"In vitro" diagnostic medical device __ Annex II List A __ Annex II List B __ Devices for self-testing __ General
Nomenclature system (preferable GMDN):	Nomenclature code:
Nomenclature text:	
Commercial name/brand name/make:	

Model number(s) or Family name:	Catalogue number(s):
Serial number range (if applicable):	Lot/batch number(s) range:
Software version number (if applicable):	
Accessories/associated devices (if applicable):	
Notified Body Identification Number:	
7. Information on trend report	
Date the trend was identified:	
Description narrative for identified trend:	
Time period of trend analysis:	
Established trigger level:	
Have any of the trended events been submitted individually as reportable events under vigilance ? __ Yes __ No	
If yes, please list how many and to which Competent Authority:	
8. Manufacturer's preliminary comments	
Manufacturer's preliminary analysis into causes of trend:	
Initial corrective actions/preventive actions implemented by the manufacturer:	
Expected date of next report	
9. Results of manufacturer's final investigation into trend	
The manufacturer's trend analysis results	
Remedial action/corrective action/preventive action/Field Safety Corrective Action	
Time schedule for the implementation of the identified actions	
Final comments from the manufacturer	
Further investigation	
10. The medical device has been distributed to the following countries Within EEA and Switzerland: __ AT __ BE __ BG __ CH __ CY __ CZ __ DE __ DK __ EE __ ES __ FI __ FR __ GB __ GR __ HR __ HU __ IE __ IS __ IT __ LI __ LT __ LU __LV __ MT __ NL __ NO __ PL __ PT __ RO __ SE __ SI __ SK __ TR All EEA, Candidate Countries and Switzerland:	
11. Comments	

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

……

Name City Date

Annex V

Adverse Incident Report – Users

Report Form for Adverse Incident – Healthcare Professionals

Medical Device Vigilance System

1. Administration information	
Recipient: Agency for Medicinal Products and Medical Devices Address: Ksaverska cesta 4 10000 Zagreb Phone: +385 1 4884 (Switchboard) Fax: +385 1 4884 110 e-mail: medpro@halmed.hr	
Classification of adverse event: __ Death __ Unexpected serious deterioration of health state __ All other adverse events that should be reported	
Identify to what other national competent authorities this report was also sent:	
2. Information on submitter of the report	
Name and surname of submitter:	
Name of healthcare setting:	
Contact name in healthcare setting	
Address:	

Postcode:	City:
Phone:	Fax:
E-mail:	Country:
3. Manufacturer information	
Name	
Contact name	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
4. Supplier information	
Name:	
Contact name:	
Address:	
Postcode:	City:
Phone:	Fax:
E-mail:	Country:
5. Medical device information	
Risk class:	
__ Active implantable medical device __ Medical device __ "In vitro" diagnostic medical device	
Commercial name/ brand name / make:	
Model number(s) and/or catalogue number(s):	
Serial number range(s) and/or lot/batch number range(s):	
Software version number (if applicable):	
Manufacturing date/ expiry or usage date (if applicable):	
Accessories/associated devices (if applicable):	
6. Information on trend report	
Trend report file number allocated by user, or institution (if applicable):	
Date the trend was reported:	

Description narrative for reported trend:	
Number of patients concerned (if known):	Number of medical devices concerned (if known):
Current location/setting of medical device (if known):	
Medical device operator at the moment of event (choose one): __ healthcare professional __ patient __ others	
Use of medical device at the moment of event (choose one): __ initial use __ re-use of multiple use medical device __ others (please specify):	__ re-use of single medical device __ serviced or in other way renewed device __ problem detected before use
7. Patient information	
Consequences for patient:	
Additional measures relevant for patient undertaken by healthcare setting:	
Patient age at the moment of event, if applicable:	
Sex, if applicable: __ Female __ Male	
Weight in kg, if applicable:	
8. Comments	

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

……

Name City Date