Medical Device Professional User's Incident Report, Version 1.

Submit the form by email to meddev.vigilance@fimea.fi or by post to Finnish Medicines Agency, P.O. Box 55, 00034 FIMEA

Filling instructions on page five.

*** Mandatory fields**

A. Organisation information

Actor*

☐ Wellbeing services county ☐ Health care organisation ☐ Social welfare organisation ☐ Self-employed person ☐ Social welfare or health care professional ☐ Beauty therapy sector [1]
Name of organisation* [2]

Address name	Address number
City	Postal code
P.O.Box	P.O.Box postal code
Telephone number of organisation	

Incident contect person details

First name*	Last name*
Telephone number	E-mail address*
Notification submission date*	

B. Device basic information

Name of device manufacturer

Name* [3]

Device supplier name [4]

Name
Device name (or EMDN code, if known)* [5]
Device trade name*
Device model
Device identification* [6]

Other devices or accessories involved in the incident (name and manufacturer)

C. Basic information on the incident

Place of the incident* [7]

Date of incident* [8]

Name of the actor notified of the incident*

Incident reported to actor on (date)* [9]

The device in question or devices of the same production lot are available for examination*

☐ Yes ☐ No

Current location of the device

☐ In the organisation

☐ In the possession of the patient

☐ En route to the manufacturer

☐ In the possession of the manufacturer

☐ In the possession of the device supplier

☐ Discarded

☐ Implanted in the patient

☐ Other location

☐ Unknown

Classification of incident* [10]

☐ Serious public health threat

☐ Death

☐ Serious incident

☐ Incident

☐ Expected side-effect

The person injured in the incident

☐ No injury

☐ Patient, customer

☐ User

☐ Other person

D. Description of the incident

Description of the situation connected to the use of the device as a result of which the incident occurred or could have occurred.* [11]
Description of the consequences or potential consequences of the incident for the patient/customer or other person.* [12]
IMDRF device problem code of the incident (Annex A) [13]
IMDRF health effect code of the incident (Annex F) [14]
Any attachments or other additional material [15]

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Medical Device Professional User's Incident Report

A. Organisation information

Actor

[1] The beauty therapy sector refers to actors that use devices without an intended medical purpose (see MDR 745, Annex XVI). E.g. a cosmetologist.

Name of organisation

[2] 'Name of organisation' refers to the name that covers the entire organisation's activities.

B. Device basic information

Name

[3] The manufacturer name can be found on the device label or the device itself.

Device supplier name

[4] Device supplier name.

Device name (or EMDN code, if known)

[5] The device name refers to the generic name used for the device, such as an infusion pump or operating table. The EMDN can be found at https://webgate.ec.europa.eu/dynam2/emdn.

Device identification

[6] Device identification information includes serial number, UDI, software version number or product number together with the manufacturing batch number.

C. Basic information on the incident

Place of the incident

[7] If the organisation consists of several locations, input the location and actual site of the incident (e.g. specific department, clinic or other).

Date of incident

[8] "Date of the incident" refers to the time when the professional user discovered or became aware of the incident.

Incident reported to actor on (date)

[9] The professional user must notify the manufacturer, authorised representative, device supplier (the terms 'importer' or 'distributor' are used in legislation) of any incident that has or could have compromised the health of a patient, user or other person and that was caused by a medical device (for more information, refer to section 33 of the Medical Devices Act 719/2021).

Classification of incident

[10] **Serious public health threat** refers to an incident that may result in the immediate risk of death, a serious deterioration in the health of the person, or a serious illness that may require immediate remedial action. Upon the death of a patient, the notification is classified as '**Death**', even if no link between the death and the device can be reliably established at the time of the notification.

Serious incident refers to an incident in which the health of the patient, user or other person deteriorates or could have deteriorated permanently or temporarily as a result of the incident. Prolonged hospital care or delayed diagnosis of a serious illness are considered a serious deterioration in health.

Incident refers to an incident which did not result in serious consequences, but where, for example, the performance of the device or information provided with the device was inadequate.

Expected side effect refers to a side effect noted in the user instructions.

D. Description of the incident

Description of the situation connected to the use of the device as a result of which the incident occurred or could have occurred.

[11] Describe what happened. Describe the situation where the device was being used. Also describe other background information, such as the service life of the device, implementation of maintenance, exceptional circumstances, possible changes in packaging, observations related to user aptitude, or information systems, telecommunications or combinations of devices used with the device. Please note that you may not provide personal data or information that might reveal a person's identity.

Description of the consequences or potential consequences of the incident for the patient/customer or other person

[12] Describe whether there were realised or potential hazards to the patient, the person using the device or the environment where the device was being used, exposure to radiation or any other harm, such as: incorrect diagnosis, prolonged hospital treatment or procedure time or the need for additional medication. Please note that you may not provide personal data or information that might reveal a person's identity.

IMDRF device problem code of the incident (Annex A)

[13] IMDRF device problem code of the incident (https://www.imdrf.org/working-groups/adverse-event-terminology/annex-medical-device-problem)

IMDRF health effect code of the incident (Annex F)

[14] Incident IMDRF Health Impact Code (https://www.imdrf.org/working-groups/adverse-event-terminology/annex-f-health-effects-health-impact).

Any attachments or other additional material

[15] Add any appendices, e.g. an image or user manual related to the incident situation as an attachment to the email.

The Finnish Medicines Agency will not separately acknowledge the receipt of the notification.

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