\*\* FREE PREVIEW VERSION \*\*

Thank you for downloading the free preview version of the EU MDR Documentation Toolkit.

**Appendix 3 – Periodic Safety Update Report (PSUR)**

|  |  |
| --- | --- |
| Medical device(s) covered by the PSUR |  |
| Manufacturer information |  |
| Notified Body name and organization number |  |
| PSUR reference number assigned by the manufacturer |  |
| Version number of the PSUR |  |
| Data collection period covered by the PSUR |  |

**Table of contents**

[1. Executive summary 3](#_Toc148367169)

[2. Description of devices covered by the PSUR 3](#_Toc148367170)

[3. Grouping of the devices 3](#_Toc148367171)

[4. Volume of sales 4](#_Toc148367172)

[5. Size and other characteristics of the population using the device 4](#_Toc148367173)

[5.1. Estimated size of the population using the device over time 4](#_Toc148367174)

[5.2. Characteristics of the population using the device over time 4](#_Toc148367175)

[5.3. Evaluation of device usage over time by patient groups 5](#_Toc148367176)

[5.4. Comparison with previous PSUR 5](#_Toc148367177)

[6. Post-market surveillance: Vigilance and CAPA information 5](#_Toc148367178)

[6.1. Information concerning serious incidents 5](#_Toc148367179)

[6.1.1. Total number (N) and rate (%) of serious incidents by IMDRF Adverse Event Terminology (AET) Annex A – Medical Device Problem by time and region over time 5](#_Toc148367180)

[6.1.2. Total number (N) and rate (%)\* of the serious incidents by IMDRF AET Annex C - Cause Investigation - Investigation Findings by time and region over time 6](#_Toc148367181)

[6.1.3. IMDRF AET Annex F – Health Effects – Health Impact code of the serious incidents by IMDRF AET Annex D – Investigation Conclusion in last 4 years 6](#_Toc148367182)

[6.1.4. Summary 7](#_Toc148367183)

[6.2. Information from Trend Reports 7](#_Toc148367184)

[6.3. Information from Field Safety Corrective Actions (FSCAs) 7](#_Toc148367185)

[6.3.1. FSCA initiated in current reporting period and open FSCAs 7](#_Toc148367186)

[6.3.2. Comparison with previous PSURs 7](#_Toc148367187)

[6.4. Preventive and / or Corrective Actions (CAPAs) 7](#_Toc148367188)

[6.4.1. CAPA initiated in the current reporting period and open CAPAs 7](#_Toc148367189)

[7. Post-Market Surveillance 8](#_Toc148367190)

[7.1. General Post-Market Clinical Follow-up (PMCF) information 8](#_Toc148367191)

[7.1.1. Feedbacks and complaints from users, distributors and importers 8](#_Toc148367192)

[7.1.2. Scientific literature review of relevant specialist or technical literature 8](#_Toc148367193)

[7.1.3. Public databases and / or registry data 8](#_Toc148367194)

[7.1.4. Publicly available information about similar medical devices 9](#_Toc148367195)

[7.1.5. Other data sources 9](#_Toc148367196)

[7.2. Specific Post-Market Clinical Follow-up (PMCF) information 9](#_Toc148367197)

[7.3. Summary of findings and conclusions of the PSUR 9](#_Toc148367198)

# Executive summary

|  |
| --- |
| A brief description and status of actions taken by the [manufacturer] based on the previous PSUR |
|  |
| … |
|  |
| Change in data collection period |
|  |
| Main results of the current PSUR |
|  |

# Description of devices covered by the PSUR

|  |  |
| --- | --- |
| Device classification |  |
| … |  |
| Status of the device(s) |  |
| … |  |

…

\*\* END OF FREE PREVIEW \*\*

If you have decided that the EU MDR Documentation Toolkit is the right choice for your company, please see the table below to choose the toolkit with the required expert support level.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Toolkit with expert support** | **Toolkit with extended support** | **Power toolkit** |
|  | **597 EUR** | **1097 EUR** | **2097 EUR** |
| **31 document templates compliant with EU MDR 2017/745** | **🗸** | **🗸** | **🗸** |
| **Email support** | 10 questions per month | Unlimited | Unlimited |
| **One-on-one support with an ISO 13485 / EU MDR expert** | 1 hour | 5 hours | 15 hours |
| **Expert review (completed documents)** | 1 document | 5 documents | 15 documents |
| **Pre-audit check** | **X** | **🗸** | **🗸** |
|  | [**ORDER NOW**](https://shop.advisera.com/order/checkout.php?PRODS=43070390&QTY=1&CART=1&CARD=1&SHORT_FORM=1?utm_source=toolkit-document-preview&utm_medium=downloaded-content&utm_campaign=eu-mdr-templates&utm_term=toolkit-with-expert-support&utm_content=lang-en) | [**ORDER NOW**](https://shop.advisera.com/order/checkout.php?PRODS=43070530&QTY=1&CART=1&CARD=1&SHORT_FORM=1?utm_source=toolkit-document-preview&utm_medium=downloaded-content&utm_campaign=eu-mdr-templates&utm_term=toolkit-with-extended-support&utm_content=lang-en) | [**ORDER NOW**](https://shop.advisera.com/order/checkout.php?PRODS=43070565&QTY=1&CART=1&CARD=1&SHORT_FORM=1?utm_source=toolkit-document-preview&utm_medium=downloaded-content&utm_campaign=eu-mdr-templates&utm_term=toolkit-with-power-support&utm_content=lang-en) |
|  | (click the link above using CTRL+click) | | |