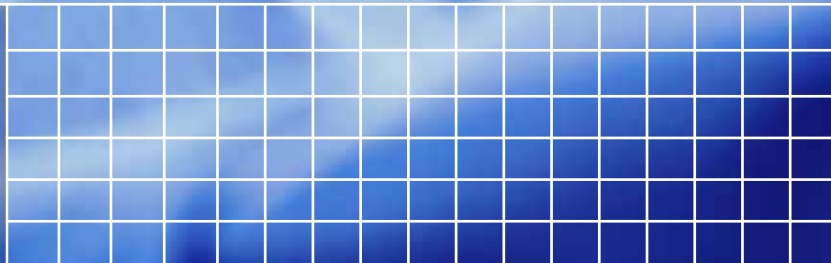




Medical Device Regulation (EU) 2017/745  
In Vitro Diagnostic Medical Device  
Regulation (EU) 2017/746  
**Post-Market Surveillance Requirements**  
**Guide to Manufacturers**

Any reproduction or further dissemination of this publication is not allowed, unless prior written approval is provided by the Content Manager of MDlaw.eu (contact: [mdlaw@obelis.net](mailto:mdlaw@obelis.net)).

POWERED BY OBELIS GROUP



# Content

- 1 General:** ..... **3**
- 2 Risk management, clinical evaluation, post market surveillance (PMS) and post market clinical follow-up (PMCF)** ..... **5**
- 3 PMS system documentation** ..... **6**
  - 3.1 Scope ..... 6
  - 3.2 Role and responsibilities ..... 7
  - 3.3 Applicable requirements..... 7
- 4 Post-Market Surveillance process** ..... **7**
  - 4.1 Definition: ..... 7
  - 4.2 Description ..... 7
  - 4.3 PMS process flow chart ..... 10
- 5 Post-Market surveillance plan** ..... **11**
- 6 Post-Market Clinical Follow up process** ..... **13**
  - 6.1 Post-Market Clinical Follow up plan ..... 14
  - 6.2 Post marketing Clinical Follow-Up Studies ..... 15
- 7 Periodic Safety Update Report (PSUR) and post market surveillance report (PMSR)** ..... **16**
  - 7.1 Scope ..... 16
  - 7.2 Report Review ..... 16
  - 7.3 Report Distribution..... 16
  - 7.4 PSUR content ..... 16
  - 7.5 PMSR content..... 17
- 8 Product incident report** ..... **20**
- 9 Vigilance reporting** ..... **21**
  - 9.1 Manufacturer Incident report (MIR): ..... 23
  - 9.2 Periodic summary report (PSR) ..... 23
  - 9.3 Trend reporting..... 24
  - 9.4 Field Safety Corrective Action (FSCA) ..... 24
- 10 Tracking system** ..... **25**
- 11 Training** ..... **26**
- 12 Person responsible for regulatory compliance (PRRC)** ..... **26**
- 13 Preparing for MDR Implementation with regards to PMS and PMCF** ... **27**

# Medical Device Regulation (EU) 2017/745 In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 Post-Market Surveillance Requirements **Guide to Manufacturers**

## 1. General

'Post-market surveillance' is defined in the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) as...

Manufacturers should...


## 2. Risk management, clinical evaluation, post market surveillance (PMS) and post-market clinical follow-up (PMCF)

...
