Medicines & Healthcare products Regulatory Agency

Post-market surveillance (PMS) obligations by medical device type

Table of requirements applying to different devices

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Introduction

The new set of regulations The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 amends the UK Medical Devices Regulations (MDR) 2002 by inserting a new Part 4A on post-market surveillance (PMS) requirements for medical devices, including in vitro diagnostic (IVD) devices and active implantable medical devices which apply within Great Britain (GB). It includes notification requirements for incidents, and preventive and corrective actions taking place after the device is first approved for the GB market.

These requirements do not apply to devices subject to clinical investigation, performance evaluation or exceptional use authorisation in GB. They also do not apply to medical devices manufactured in-house by healthcare establishments (regardless of whether custom-made) which should follow the existing Guidance provided on MHRA's website.

Comprehensive guidance on this topic can be found here: Medical devices: post-market surveillance - GOV.UK.

The following guidance documents provide tables detailing the PMS requirements for different device types.

General medical device

Type of device	General medical device	General medical device	General medical device
Relevant part and regulation of UK MDR 2002	Part 2	Part 2, Regulation 19B	Part 2, Regulation 19C
Basis for conformity assessment (UKCA, EU MDD/IVDD/AIMDD or EU MDR/IVDR)	UKCA	EU MDD	EU MDR
PMS System (44ZE)	All risk classes	All risk classes	All risk classes
PMS Plan (44ZF)	All risk classes	All risk classes	All risk classes
Corrective and Preventative Actions (44ZG)	All risk classes	All risk classes	All risk classes
Initial reporting of serious incidents (44ZH)	All risk classes	All risk classes	All risk classes
Investigation and final reporting of serious incidents (44ZI)	All risk classes	All risk classes	All risk classes
FSCA & FSN (44ZJ)	All risk classes	All risk classes	All risk classes
FSCA outside of Great Britain (44ZK)	All risk classes	All risk classes	All risk classes
PMS reports (44ZL)	Class I	Class I	Class I
PSUR reports (44ZM)	Class IIa, IIb, III	Class IIa, IIb, III	Class IIa, IIb, III
Trend Reporting (44 ZN)	All risk classes	All risk classes	All risk classes
Reports from HCPs, user, patients (44ZO)	All risk classes	All risk classes	All risk classes
Analysis of information under Part 4A (44ZP)	All risk classes	All risk classes	All risk classes
Retention of PMS documentation (44ZQ)	All risk classes	All risk classes	All risk classes

Active implantable medical devices

Type of device	Active Implantable medical devices	Active Implantable medical devices	Active Implantable medical devices
Relevant part and regulation of UK MDR 2002	Part 3	Part 3, Regulation 30A	Part 3 and Regulation 19C of Part 2
Basis for conformity assessment (UKCA, EU MDD/IVDD/AIMDD or EU MDR/IVDR)	UKCA	EU AIMDD	EU MDR
PMS System (44ZE)	Class III	Class III	Class III
PMS Plan (44ZF)	Class III	Class III	Class III
Corrective and Preventative Actions (44ZG)	Class III	Class III	Class III
Initial reporting of serious incidents (44ZH)	Class III	Class III	Class III
Investigation and final reporting of serious incidents (44ZI)	Class III	Class III	Class III
FSCA & FSN (44ZJ)	Class III	Class III	Class III
FSCA outside of Great Britain (44ZK)	Class III	Class III	Class III
PMS reports (44ZL)	N/A	N/A	N/A
PSUR reports (44ZM)	Class III	Class III	Class III
Trend Reporting (44 ZN)	Class III	Class III	Class III
Reports from HCPs, user, patients (44ZO)	Class III	Class III	Class III
Analysis of information under Part 4A (44ZP)	Class III	Class III	Class III
Retention of PMS documentation (44ZQ)	Class III	Class III	Class III

In Vitro diagnostic (IVD) devices

Type of device	In Vitro Diagnostic devices	In Vitro Diagnostic devices	In Vitro Diagnostic devices
Relevant part and regulation of UK MDR 2002	Part 4	Part 4, Regulation 44ZA	Part 4, Regulation 44ZB
Basis for conformity assessment (UKCA, EU MDD/IVDD/AIMDD or EU MDR/IVDR)	UKCA	EU IVDD	EU IVDR
PMS System (44ZE)	All risk classes	All risk classes	All risk classes
PMS Plan (44ZF)	All risk classes	All risk classes	All risk classes
Corrective and Preventative Actions (44ZG)	All risk classes	All risk classes	All risk classes
Initial reporting of serious incidents (44ZH)	All risk classes	All risk classes	All risk classes
Investigation and final reporting of serious incidents (44ZI)	All risk classes	All risk classes	All risk classes
FSCA & FSN (44ZJ)	All risk classes	All risk classes	All risk classes
FSCA outside of Great Britain (44ZK)	All risk classes	All risk classes	All risk classes
PMS reports (44ZL)	General IVD	General IVD	Class A and B
PSUR reports (44ZM)	List A, List B	List A, List B	Class C and D
Trend Reporting (44 ZN)	All risk classes	All risk classes	All risk classes
Reports from HCPs, user, patients (44ZO)	All risk classes	All risk classes	All risk classes
Analysis of information under Part 4A (44ZP)	All risk classes	All risk classes	All risk classes
Retention of PMS documentation	All risk classes	All risk classes	All risk classes

(44ZQ)	

Custom-made devices

Please note manufacturers can no longer place an EU AIMDD or EU MDD compliant custom-made device on the GB market (or EU or Northern Ireland). This has been the case since 26 May 2021 and the PMS regulations do not change this – they allow for **continued** acceptance of CE marked and EU compliant devices currently permitted on the GB market

Custom made devices are exempt from the following requirements of the PMS Plan: paragraphs 3, g & h.

Type of device	Custom-made devices (GMDs & AIMD)	Custom-made devices (GMD)	Custom-made devices (AIMD)	Custom-made devices (GMDs & AIMD)
Relevant part and regulation of UK MDR 2002	Part 2 and Part 3	Part 2	Part 3	Part 3 and Regulation 19C of Part 2
Basis for conformity assessment (UKCA, EU MDD/IVDD/AIMDD or EU MDR/IVDR)	UKCA	EU MDD	EU AIMDD	EU MDR
PMS System (44ZE)	All risk classes	N/A	N/A	All risk classes
PMS Plan (44ZF)	All risk classes	N/A	N/A	All risk classes
Corrective and Preventative Actions (44ZG)	All risk classes	N/A	N/A	All risk classes
Initial reporting of serious incidents (44ZH)	All risk classes	N/A	N/A	All risk classes
Investigation and final reporting of serious incidents (44ZI)	All risk classes	N/A	N/A	All risk classes
FSCA & FSN (44ZJ)	All risk classes	N/A	N/A	All risk classes
FSCA outside of Great Britain (44ZK)	N/A	N/A	N/A	N/A
PMS reports (44ZL)	N/A	N/A	N/A	N/A

PSUR reports (44ZM)	N/A	N/A	N/A	N/A
Trend Reporting (44 ZN)	N/A	N/A	N/A	N/A
Reports from HCPs, user, patients (44ZO)	All risk classes	N/A	N/A	All risk classes
Analysis of information under Part 4A (44ZP)	All risk classes	N/A	N/A	All risk classes
Retention of PMS documentation (44ZQ)	All risk classes	N/A	N/A	All risk classes

Systems and procedure packs

Regulation 44ZL and Regulation 44ZM do not apply to a relevant device which is a system or procedure pack, unless the system or procedure pack incorporates a medical device which does not bear a UKCA marking or a CE marking; or the chosen combination of medical devices is not compatible in view of their original intended use.

Type of device	Systems and procedure packs	Systems and procedure packs	Systems and procedure packs
Relevant part and regulation of UK MDR 2002	UKCA	EU MDD	EU MDR
Basis for conformity assessment (UKCA, EU MDD/IVDD/AIMDD or EU MDR/IVDR)	All risk classes	All risk classes	All risk classes
PMS System (44ZE)	All risk classes	All risk classes	All risk classes
PMS Plan (44ZF)	All risk classes	All risk classes	All risk classes
Corrective and Preventative Actions (44ZG)	All risk classes	All risk classes	All risk classes
Initial reporting of serious incidents (44ZH)	All risk classes	All risk classes	All risk classes
Investigation and final reporting of serious incidents (44ZI)	All risk classes	All risk classes	All risk classes

FSCA & FSN (44ZJ)	All risk classes	All risk classes	All risk classes
FSCA outside of Great Britain (44ZK)	All risk classes	All risk classes	All risk classes
PMS reports (44ZL)	Class I	Class I	Class I
PSUR reports (44ZM)	Class IIa, IIb and III	Class IIa, IIb and III	Class IIa, IIb and III
Trend Reporting (44 ZN)	All risk classes	All risk classes	All risk classes
Reports from HCPs, user, patients (44ZO)	All risk classes	All risk classes	All risk classes
Analysis of information under Part 4A (44ZP)	All risk classes	All risk classes	All risk classes
Retention of PMS documentation (44ZQ)	All risk classes	All risk classes	All risk classes

Further guidance

For further guidance on the changing PMS requirements please refer to Medical devices: post-market surveillance - GOV.UK.