Medicines &
Healthcare products
Regulatory Agency

Information for manufacturers of medical devices on post-market surveillance, reporting adverse incidents and field safety corrective actions to the MHRA.

MHRA's full guidance

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

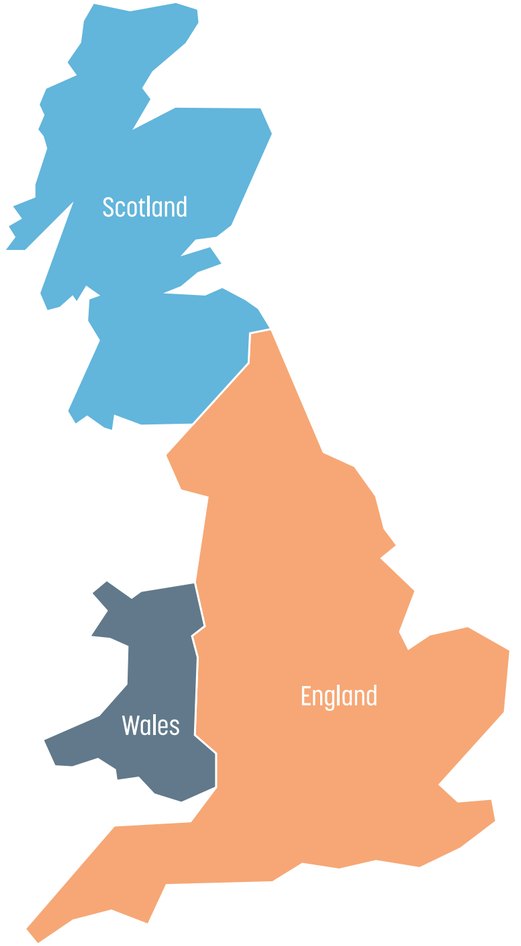
✓ **The obligations apply to England, Scotland and Wales.**

✗ **These requirements do not apply to devices subject to**

- clinical investigation,
- performance evaluation or
- exceptional use authorisation in Great Britain (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 on in-house manufacture of medical devices in Great Britain (GB).



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

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

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

Type of device	Relevant part & regulation of UK MDR 2002	Basis for conformity assessment (UKCA, EU MDD/IVDD /AIMDD or EU MDR/IVDR)	PMS System (Reg 44ZE)	PMS Plan (Reg 44ZF)	Corrective & Preventative Actions (Reg 44ZG)	Initial reporting of serious ncidents (Reg 44ZH)	Investigation & final reporting of serious incidents (Reg 44ZI)	FSCA & FSN (Reg 44ZJ)	FSCA outside of Great Britain (Reg 44ZK)	PMS reports (Reg 44ZL)	PSUR reports (Reg 44ZM)	Trend Reporting (Reg 44 ZN)	Reports from HCPs, user, patients (Reg 44ZO)	Analysis of information under Part 4A (Reg 44ZP)	Retention of PMS documentation (Reg 44ZQ)
Custom - made Devices	Part 2	UKCA	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	N/A	N/A	N/A	N/A	All risk classes	All risk classes	All risk classes
	Part 2	EU MDD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Part 3	EU AIMDD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Part 2, Regulation 19C	EU MDR	All risk classes[1]	All risk classes[2]	All risk classes	All risk classes	All risk classes	All risk classes	N/A	N/A	N/A	N/A	All risk classes	All risk classes	All risk classes

1. 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 SI doesn't change this – it allows for continued acceptance of CE marked and EU compliant devices currently permitted on the GB market.

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

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Systems and Procedure Packs	Part 2	UKCA	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	Class I [3]	Class IIa, IIb and III [3]	All risk classes	All risk classes	All risk classes	All risk classes
	Part 2, Regulation 19B	EU MDD	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	Class I	Class IIa, IIb and III	All risk classes	All risk classes	All risk classes	All risk classes
	Part 2, Regulation 19C	EU MDR	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	All risk classes	Class I	Class IIa, IIb and III	All risk classes	All risk classes	All risk classes	All risk classes

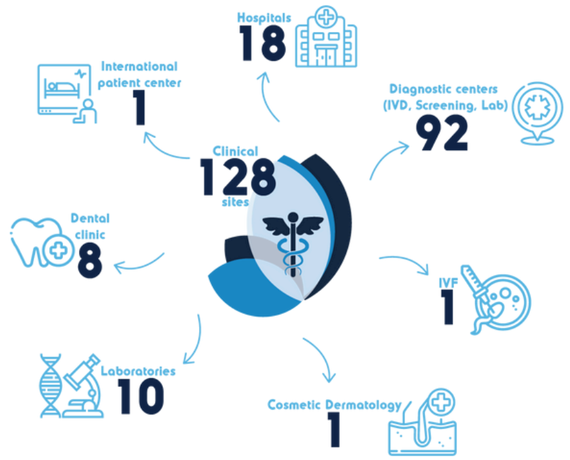
3. Only applies to system or procedure packs which are required to be either UKCA or CE-marked in order to be placed on the market.

How can Evnia help?

Evnia introduces a paradigm shift in the MedTech consulting services by offering expert medical device life cycle management service.

We support manufacturers throughout the medical device development roadmap. From the early concept and design stages to verification and validation, until market access and post-market adulthood, **Evnia enables compliance and ensures audit and inspection readiness**.

Founded in 2015 in Copenhagen, Evnia has become **the missing link between manufacturers, regulators and investors** working for healthcare innovation and the improvement of patients quality of care and life.



Our know-how and cluster of interconnected services brings to the table **a comprehensive, time- and cost-effective service**. A **one-stop-shop solution to address strategic and operational needs throughout the lifetime of a medical device** or an in-vitro diagnostic.

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