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Regulatory Intelligence Paper

Table of Content:

Note: This paper is a support document which helps companies to be compliant according to ISO 13485: 2016 (Chapter 5.6 Management Review). But Regulatory Globe GmbH does not give any guarantee regarding completeness and correctness of this document and is also not responsible for any missing information who can affect the user/company. Each user/company is responsible by them self to have all required regulations and standards in place.

1. Europe

Topic 1:	**MDCG 2023-3 rev.2 - Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 under Regulation (EU) 2017/746**		
Source:	EU doc.room		
Relevant for:	☒ General		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Updated:** - Question 1: Footnote 8 has been amended to align with Regulation (EU) 2024/1860 - Question 21: Reference to 'Eudamed vigilance (VGL) module' is amended to 'Eudamed Post-market surveillance and Vigilance module (VGL module)' - Footnote 34: Mention of '48 working hours' replaced with 'allow 48 hours (equivalent to two weekdays)'		
Scope / Description:	*This document provides clarification and guidance on the implementation of vigilance requirements related to reporting of incidents and field safety corrective actions for medical devices under the EU Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (IVDR) 2017/746.*		
Information Issued:	January 7, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 2:	**Revised versions of the PAR templates and the form to apply for designation as NB as well as their annexes are available in the Notified Bodies section**
Source:	EU doc.room
Relevant for:	☒ Notified Bodies
Could affect following device type areas:	☒ General
Key Topics:	▪ **Updated templates:** - MDCG 2024-7 Rev.1 - MDCG 2024-8 Rev.1
Scope / Description:	*These documents provides a template for Designating Authorities (DAs) to review applications from Conformity Assessment Bodies (CABs) seeking designation as Notified Bodies under the EU MDR 2017/745 or EU IVDR 2017/746. It covers the preliminary assessment of CABs' documentation before an on-site assessment is conducted.*
Information Issued:	January 10, 2025
Implementation deadline:	N/A

Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 3:	**MDCG 2025-1 EMDN Ad hoc procedure**		
Source:	EU doc.room		
Relevant for:	☒ Manufacturers ☒ Notified Bodies ☒ Authorized Representatives ☒ Competent Authorities		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Ad-hoc procedure for EMDN code updates**		
Scope / Description:	*This document provides a form for the submission of proposals under the ad-hoc update procedure for the European Medical Device Nomenclature (EMDN). It outlines the process and required information for requesting updates or additions to the EMDN, particularly when there's a need for new codes that cannot be accommodated by existing ones.*		
Information Issued:	January 28, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 4:	**MDCG 2025-2 EMDN update submissions from 2024 public consultation and the MDCG nomenclature working group**
Source:	EU doc.room
Relevant for:	☒ Manufacturers ☒ Importers ☒ Authorized Representatives ☒ Notified Bodies
Could affect following device type areas:	☒ General
Key Topics:	▪ **EMDN code additions and modifications** ▪ **Categorization of medical devices** ▪ **Analysis of public consultation submissions** ▪ **Updates to nomenclature structure** ▪ **Rationalization of accepted and rejected proposals**
Scope / Description:	*This document outlines the outcomes of the analysis of submissions for updates to the European Medical Device Nomenclature (EMDN). It includes accepted, partially accepted, and not accepted submissions from the 2024 public consultation and the MDCG Nomenclature working group. The document provides details on proposed changes to various medical device categories and codes within the EMDN system.*
Information Issued:	January 28, 2025
Implementation deadline:	N/A

Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 5:	**MDCG 2025-3 EMDN Version History**		
Source:	EU doc.room		
Relevant for:	☒ Manufacturers	☒ Importers	☒ Authorized Representatives
	☒ Notified Bodies		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Change history**		
Scope / Description:	*This document outlines the changing history of EMDN codes.*		
Information Issued:	January 28, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 6:	**MDCG 2021-12 FAQ on the European Medical Device Nomenclature EMDN (Rev.1)**
Source:	EU doc.room
Relevant for:	☒ Manufacturers
Could affect following device type areas:	☒ General
Key Topics:	▪ **Purpose and structure of the European Medical Device Nomenclature (EMDN)** ▪ **EMDN code assignment process for UDI-DI registration in EUDAMED** ▪ **Annual review procedure for EMDN updates** ▪ **Handling of devices with multiple EMDN codes** ▪ **Submission and evaluation process for new EMDN code proposals**
Scope / Description:	*This document provides frequently asked questions (FAQ) about the European Medical Device Nomenclature (EMDN). The EMDN aims to support the functioning of the European database on medical devices (EUDAMED) and serves regulatory purposes under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).*
Information Issued:	January 28, 2025
Implementation deadline:	N/A

Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 7:	**MDCG 2024-2 Procedures for the updates of the EMDN (Rev.1)**		
Source:	EU doc.room		
Relevant for:	☒ Manufacturers	☒ Authorized Representative	☒ Importers
	☒ Notified Bodies	☒ Distributors	
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Annual revision procedure for the EMDN, including four phases: collection of requests, evaluation, validation and endorsement, and MDCG endorsement and publication** ▪ **Actors involved in the EMDN update process (MDCG Nomenclature working group, EMDN-TT, Users)** ▪ **Pilot procedure for ad-hoc updates of the EMDN requiring expedited review** ▪ **Submission and evaluation process for EMDN update requests**		
Scope / Description:	*This document outlines the procedures for annual revisions and ad-hoc expedited updates to the European Medical Device Nomenclature (EMDN). It lays out the processes for both the annual review and the procedure for ad-hoc requests requiring an expedited review. The EMDN is established by Article 26 of Regulation (EU) 2017/745 (MDR) and Article 23 of Regulation (EU) 2017/746 (IVDR).*		
Information Issued:	January 28, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 8:	**MDCG 2021-15 Applying for designation as notified body under the medical devices regulation (MDR) (Rev.1)**		
Source:	EU doc.room		
Relevant for:	☒ Manufacturers	☒ Authorized Representative	☒ Importers
	☒ Notified Bodies	☒ Distributors	☒ Conformity assessment bodies (primarily)
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Organizational and general requirements for conformity assessment bodies** ▪ **Quality management system requirements** ▪ **Resource requirements, including personnel qualifications and subcontractor management** ▪ **Process requirements for conformity assessment activities, including application review, assessment procedures, and post-certification activities**		
Scope / Description:	*This document is an application form and checklist for conformity assessment bodies applying to be designated as notified bodies under the EU Medical Device Regulation (MDR) 2017/745. It outlines the information and supporting documentation required across several areas related to organizational requirements, quality management system, resource requirements, and process requirements for conformity assessments.*		
Information Issued:	January 28, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 9:	**MDCG 2021-16 Applying for designation as notified body under the in-vitro diagnostic regulation (IVDR) (Rev.1)**
Source:	EU doc.room
Relevant for:	☒ Notified Bodies ☒ Conformity assessment bodies
Could affect following device type areas:	☒ General
Key Topics:	▪ **Organizational and general requirements for CABs** ▪ **Quality management system requirements** ▪ **Resource requirements and personnel qualifications** ▪ **Process requirements for conformity assessment activities** ▪ **Documentation and procedures for surveillance and post-certification monitoring**
Scope / Description:	*This document is an application form for conformity assessment bodies (CABs) seeking designation as a notified body under the EU's In Vitro Diagnostic Medical Devices Regulation (IVDR). It requests detailed information and supporting documentation related to organizational, quality management system, resource, and process requirements for notified bodies.*
Information Issued:	January 28, 2025
Implementation deadline:	N/A

Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Other important updates:

Document:	Updates:	Note:
Directive 2011/65/EU: RoHS Directive as applicable to pcb assemblies, inclusive of recast, specifically Annex IV, inclusive of 2014/13/EU (Version: 01.01.2025)	Updated on 01.01.2025	Link
EU MDR 2017/745 Regulation (EU) 2017/745 of the European Parliament and of the	Updated on 10.01.2025	Link

Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) (10.01.2025)		
EU IVDR 2017/746 Consolidated text: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) (10.01.2025)	Updated on 10.01.2025	Link

2. Japan

Topic 1:	**No relevant news related to Japan**		
Source:	mhlw.go.jp		
Relevant for:	☒ N/A		
Could affect following device type areas:	☒ N/A		
Key Topics:	▪ **N/A**		
Scope / Description:	*N/A*		
Information Issued:	N/A		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

3. Canada

Topic 1:	**No relevant news related to Canada**		
Source:	Canada.ca		
Relevant for:	☒ N/A		
Could affect following device type areas:	☒ N/A		
Key Topics:	▪ **N/A**		
Scope / Description:	*N/A*		
Information Issued:	N/A		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

4. Brazil

Topic 1:	**No relevant news related to Brazil**		
Source:	ANVISA.gov.br		
Relevant for:	☒ N/A		
Could affect following device type areas:	☒ N/A		
Key Topics:	▪ **N/A**		
Scope / Description:	*N/A*		
Information Issued:	N/A		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

5. Australia

Topic 1:	**No relevant news related to Australia**		
Source:	TGA.gov.au		
Relevant for:	☒ N/A		
Could affect following device type areas:	☒ N/A		
Key Topics:	▪ **N/A**		
Scope / Description:	*N/A*		
Information Issued:	N/A		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

6. USA

Topic 1:	**Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act**		
Source:	U.S. Food & Drug Administration		
Relevant for:	☒ Manufacturers (IVD/MD)		
Could affect following device type areas:	☒ Life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery	☒ Specific to diagnosing, preventing, or treating a debilitating disease or condition	
Key Topics:	▪ **Requirements for manufacturers to notify FDA of potential supply disruptions** ▪ **Information to be included in 506J notifications** ▪ **FDA's process for determining device shortages** ▪ **How FDA uses information from 506J notifications** ▪ **Consequences of failure to notify FDA**		
Scope / Description:	*This guidance provides recommendations for medical device manufacturers on notifying the FDA of permanent discontinuances or interruptions in manufacturing that are likely to cause meaningful supply disruptions of certain devices during or in advance of a public health emergency.*		
Information Issued:	January 7, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 2:	**Premarket Approval Application and Humanitarian Device Exemption Modular Review**		
Source:	U.S. Food & Drug Administration		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ PMA devices ☒ HDE devices		
Key Topics:	▪ **Process for submitting a modular PMA or HDE** ▪ **Content and review of PMA or HDE shells** ▪ **Submission and review of individual modules** ▪ **Conversion of completed modular applications to original PMA or HDE** ▪ **User fee considerations for modular review**		
Scope / Description:	*This guidance document provides information on the Premarket Approval Application (PMA) and Humanitarian Device Exemption (HDE) modular review program. It outlines procedures for submitting or reviewing a modular PMA or HDE, which is an alternative to the preparation, submission, and evaluation of traditional PMAs and HDEs.*		
Information Issued:	January 13, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

7. UK

Topic 1:	**The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024: examples of incidents to report under the vigilance system**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Examples of reportable incidents for various types of medical devices** ▪ **Rationale for reporting specific types of incidents** ▪ **Guidance on when to report incidents even if root cause or device availability is unclear** ▪ **Reporting requirements for trends in foreseeable or expected events**		
Scope / Description:	*This guidance document provides examples of incidents that should be reported under the vigilance system as part of the post-market surveillance requirements for medical devices in Great Britain.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 2:	**Guidance for manufacturers on reporting adverse incidents involving software as a medical device under the vigilance system**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Software		
Key Topics:	▪ **Types of reportable adverse incidents for SaMD** ▪ **Examples of performance issues and other reportable incidents** ▪ **Reporting procedures (individual reports, periodic summary reports, trend reports)** ▪ **Use of the MORE portal for submitting reports**		
Scope / Description:	*This guidance document provides information for manufacturers of software as a medical device (SaMD) on reporting adverse incidents under the vigilance system. It complements the requirements of SI 2024 No. 1368 and should be read in conjunction with that regulation.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 3:	**Device-specific vigilance guidance: in vitro diagnostic (IVD) blood glucose monitors, covering point of care testing and home use**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers (IVD)		
Could affect following device type areas:	☒ Blood glucose monitors		
Key Topics:	▪ **Types of reportable adverse incidents for IVD blood glucose monitors** ▪ **Information to be included in incident reports** ▪ **Manufacturer's investigation requirements** ▪ **Final vigilance report content**		
Scope / Description:	*This guidance document provides information for manufacturers of in vitro diagnostic (IVD) blood glucose monitors, covering point of care testing and home use. It outlines specific scenarios to consider when determining if an incident is reportable and what to include in the report. The document complements the requirements of SI 2024 No. 1368 and should be read in conjunction with that regulation.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 4:	**Regulation of devices in Northern Ireland**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ General		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Updated:** - Updated to reflect the laying of The Medical Devices (Post-market Surveillance requirements) (Amendment) Regulations 2024.		
Scope / Description:	*Information about the EU Regulations and their implementation in Northern Ireland.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 5:	**The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024: guidance on periodic safety update reports (PSUR) (regulation 44ZM) for approved bodies**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Approved Bodies ☒ Manufacturers (indirectly)		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **PSUR content review by approved bodies** ▪ **Evaluation of manufacturer's post-market surveillance data analysis** ▪ **Assessment of benefit-risk profiles and emerging risks** ▪ **Approved body's conclusion and potential actions based on PSUR review** ▪ **Impact on UKCA certification**		
Scope / Description:	*This guidance document provides information for approved bodies on their obligations regarding Periodic Safety Update Reports (PSURs) under regulation 44ZM. It applies when approved bodies have a contract with a medical device manufacturer and have issued a UK Conformity Assessed (UKCA) conformity assessment certificate for a device placed on the Great Britain market.* *Link to document: The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 6:	**Device-specific vigilance guidance: breast implants**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Breast Implant		
Key Topics:	▪ **Reportable incidents related to breast implants** ▪ **Clinical and symptomatic issues to be reported individually** ▪ **Device-related issues to be reported individually** ▪ **Incidents that may be included in periodic summary reports (PSR)** ▪ **Reporting timescales and frequencies for different types of incidents**		
Scope / Description:	*This document provides guidance for manufacturers of breast implants. It outlines specific scenarios to consider when determining if an incident is reportable. The aim of this guidance is to complement the requirements of SI 2024 No. 1368 and should be read in conjunction with this regulation and guidance on post-market surveillance.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 7:	**Device-specific vigilance guidance: neurostimulators**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Neurostimulators		
Key Topics:	▪ **Reportable incidents for individual reporting** ▪ **Incidents that may be included in periodic summary reports (PSR)** ▪ **Reporting frequency and timescales for different types of incidents** ▪ **Examples of device performance problems associated with neurostimulators** ▪ **Guidance on when to report significant increases in frequency or severity of incidents**		
Scope / Description:	*This document provides guidance for manufacturers of neurostimulators. It outlines specific scenarios to consider when determining if an incident is reportable. The guidance complements the requirements of SI 2024 No. 1368 and should be read in conjunction with this regulation and guidance on post-market surveillance.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 8:	**Custom-made devices in Great Britain**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Custom made devices		
Key Topics:	▪ **Conformity assessment requirements for custom-made devices** ▪ **Post-market surveillance system requirements** ▪ **Reporting of incidents and field safety corrective actions** ▪ **Registration requirements for manufacturers of custom-made devices** ▪ **Examples of custom-made devices and their prescribers/manufacturers**		
Scope / Description:	*This guidance applies to medical devices placed on the market in Great Britain (England, Wales, and Scotland). It aims to help manufacturers understand compliance requirements for the manufacture of custom-made active implantable medical devices or custom-made medical devices. The document is based on the UK Medical Devices Regulations 2002 as they apply in Great Britain (SI 2002 No 618, as amended) (UK MDR 2002).*		
Information Issued:	January 15, 2025		
Implementation deadline:	June 16, 2025		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 9:	**Regulating medical devices in the UK**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ General		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Updated:** - Updated to reflect the laying of The Medical Devices (Post-market Surveillance requirements) (Amendment) Regulations 2024.		
Scope / Description:	*What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 10:	**Medical devices: how to comply with the legal requirements in Great Britain**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ General		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Updated:** - Updated to reflect the laying of The Medical Devices (Post-market Surveillance requirements) (Amendment) Regulations 2024.		
Scope / Description:	*What you need to know before you can place a medical device on the Great Britain market with a UKCA mark.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 11:	**Device-specific vigilance guidance: intraocular lenses**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ General		
Could affect following device type areas:	☒ Intraocular Lenses		
Key Topics:	▪ **Updated:** - Updated to reflect the laying of The Medical Devices (Post-market Surveillance requirements) (Amendment) Regulations 2024.		
Scope / Description:	*What you need to know before you can place a medical device on the Great Britain market with a UKCA mark.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 12:	**In vitro diagnostic medical devices: guidance on legislation**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers (IVD)	☒ UK Responsible Persons	☒ UK approved bodies
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Definition and scope of IVDs under UK MDR 2002** ▪ **Conformity assessment processes and classification of IVDs** ▪ **Essential requirements and UKCA marking** ▪ **Registration and UK Responsible Person obligations** ▪ **Post-market surveillance and vigilance procedures**		
Scope / Description:	*This document outlines the current controls on the sale and supply of in vitro diagnostic (IVD) medical devices in Great Britain (England, Wales, and Scotland). It explains the main features of the requirements for IVDs set out in Part IV of the UK Medical Devices Regulations 2002 (as amended) (UK MDR 2002). The guidance covers various aspects of IVD regulation, including definitions, conformity assessment processes, and other regulatory requirements.*		
Information Issued:	January 15, 2025		
Implementation deadline:	June 16, 2025		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 13:	**Device-specific vigilance guidance: joint replacement implants**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Joint replacement implants		
Key Topics:	▪ **Reporting requirements for joint replacement revisions** ▪ **Criteria for determining reportable incidents** ▪ **Guidance on specific scenarios (e.g., infection, misalignment, mechanical failure, aseptic loosening)** ▪ **Reporting of anomalous soft tissue changes and systemic effects**		
Scope / Description:	*This document provides guidance for manufacturers of joint replacement implants. It outlines specific scenarios to consider when determining if an incident is reportable. The guidance complements the requirements of SI 2024 No.1368 and should be read in conjunction with this regulation and guidance on post-market surveillance. It does not replace or extend these requirements.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 14:	**Guidance on applying human factors to medical devices**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Updated:** - Updated to reflect the laying of The Medical Devices (Post-market Surveillance requirements) (Amendment) Regulations 2024 .		
Scope / Description:	*Guidance on the importance of applying human factors to medical devices, so they are designed and optimised to minimise patient and user safety risks.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 15:	**Device-specific vigilance guidance: devices for cardiac ablation**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Cardiac ablation		
Key Topics:	▪ **Reporting requirements for individual incidents** ▪ **Incidents that may be included in periodic summary reports (PSR)** ▪ **Clinical and device-related issues requiring reporting** ▪ **IMDRF Annex A and E codes associated with reportable incidents** ▪ **Guidance on reporting significant increases in frequency or severity of incidents**		
Scope / Description:	*This document provides guidance for manufacturers of devices for cardiac ablation. It outlines specific scenarios to consider when determining if an incident is reportable. The guidance complements the requirements of SI 2024 No. 1368 and should be read in conjunction with this regulation and guidance on post-market surveillance.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 16:	**Device-specific vigilance guidance: insulin infusion pumps and integrated meter systems**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ Insulin fusion pumps		
Key Topics:	▪ **Reporting requirements for individual incidents (clinical/symptomatic and device-related)** ▪ **Incidents that may be included in periodic summary reports (PSR)** ▪ **Reporting of significant increases in frequency or severity of incidents** ▪ **IMDRF Annex A and E codes associated with reportable incidents**		
Scope / Description:	*This document provides guidance for manufacturers of insulin infusion pumps and integrated meter systems. It outlines specific scenarios to consider when determining if an incident is reportable. The scope includes insulin infusion pumps and integrated meter systems (insulin infusion pumps operating in combination with a blood glucose monitoring system). Continuous glucose monitoring devices, infusion sets, and cartridges are not included in the scope.*		
Information Issued:	January 15, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 17:	**Implementation of the future regulations**		
Source / Doc.:	UK.GOV		
Relevant for:	☒ General		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Phased implementation of new regulatory framework** ▪ **Transitional arrangements for CE marked devices** ▪ **Introduction of strengthened Post-Market Surveillance requirements** ▪ **Updates to pre-market requirements and device classifications** ▪ **Guidance updates for the MedTech sector**		
Scope / Description:	*This document outlines the government's plan to introduce new regulations for medical devices in the UK. It provides a roadmap for implementing a future regulatory framework that prioritizes patient safety, ensures access to needed medical devices, and maintains the UK's attractiveness for medical technology innovators. The document describes a phased approach to implementation, including transitional arrangements and new post-market surveillance requirements.*		
Information Issued:	January 15, 2025		
Implementation deadline:	Important dates: - Further Statutory instruments will follow in 2025 and 2026 - CE marked medical devices will be accepted on the Great Britain market until 30 June 2030		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

8. Switzerland

Topic 1:	**Information sheet: Obligations Economic Operators CH (Version 6.0)**		
Source / Doc.:	Swissmedic		
Relevant for:	☒ General (IvDO)		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Update:** - Amendment due to new version of the IvDO of the 01.01.2025		
Scope / Description:	*This document outlines the obligations and requirements for economic operators (manufacturers, authorized representatives, importers, distributors) regarding medical devices and in vitro diagnostic devices in Switzerland under the new Medical Devices Ordinance (MedDO) and IVD Ordinance (IvDO). It covers aspects like registration, verifying conformity, traceability, incident reporting, labeling, and transitional provisions.*		
Information Issued:	January 1, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 2:	**Information sheet: Procurement of medical devices in healthcare institutions (Version 5.2)**		
Source / Doc.:	Swissmedic		
Relevant for:	☒ Healthcare institutions ☒ Importers	☒ Manufacturers	☒ Swiss authorized representatives
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Conformity assessment and CE/MD marking requirements for medical devices** ▪ **Responsibilities of healthcare institutions in procuring and using medical devices** ▪ **New requirements for traceability and implant cards under the updated regulations** ▪ **Roles and obligations of Swiss authorized representatives and importers** ▪ **Quality deficiencies reporting and materiovigilance obligations**		
Scope / Description:	*This information sheet is aimed at healthcare institutions (e.g., hospitals, practices, and purchasing organizations) and describes the documentation and evidence for demonstrating the conformity of medical devices. It provides guidance on the procurement of medical devices in healthcare institutions in Switzerland, covering various aspects of medical device regulation, conformity assessment, and responsibilities of healthcare institutions.*		
Information Issued:	January 1, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 3:	**FAQ on in vitro diagnostic medical device notifications (Version 2.1)**		
Source / Doc.:	Swissmedic		
Relevant for:	☒ Manufacturers (IvDO) ☒ Importers	☒ Healthcare institutions (for in-house IVDs) ☒ Distributors	☒ Authorized Representatives
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Notification requirements for different types of IVDs and economic operators** ▪ **Transitional periods for compliance with new regulations (IvDO)** ▪ **Procedures for completing notification forms, especially for in-house IVDs** ▪ **Changes in notification processes from previous regulations (IVDD to IVDR)** ▪ **Fees and timelines for notification processing**		
Scope / Description:	*It covers various aspects of the notification process, including which devices must be notified, who must notify them, and the timelines for notifications under the new IvDO (Ordinance on In Vitro Diagnostic Medical Devices).*		
Information Issued:	January 17, 2025		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 4:	**Swiss Good Practice for the Maintenance of Medical Devices (Version 2.0)**
Source / Doc.:	Swissmedic
Relevant for:	☒ Manufacturers
Could affect following device type areas:	☒ General
Key Topics:	▪ **Quality management system requirements for medical device maintenance** ▪ **Responsibilities and organization of maintenance activities** ▪ **Life cycle management of medical devices in healthcare facilities** ▪ **Risk management and vigilance related to medical device maintenance** ▪ **Specific considerations for software, networked devices, and in-house manufactured devices**
Scope / Description:	*This document provides guidelines for the maintenance of medical devices in Swiss healthcare facilities, particularly hospitals. It covers technical and administrative measures throughout a medical device's lifecycle, aiming to maintain or restore the functional and safe condition of medical devices for patients, users, and third parties. The document aligns with current legal requirements, technological standards, and good practices in the field.*
Information Issued:	January 31, 2025
Implementation deadline:	N/A

Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

9. ISO Standards

Topic 1:	**No relevant Standard updates**		
Source / Doc.:	ISO.org		
Relevant for:	☒ N/A		
Could affect following device type areas:	☒ N/A		
Key Topics:	▪ **N/A**		
Scope / Description:	*N/A*		
Information Issued:	N/A		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

10. Release

Name:	Position:	Date:	Signature:
tbd:	tbd:	tbd:	tbd:
tbd:	tbd:	tbd:	tbd:

Annex 1: ISO Standards (Status changes, related to EU harmonized standards only)

	Under development:
List of documents:	• ISO/DIS 10993-11Biological evaluation of medical devices Part 11: Tests for systemic toxicity - (Draft – Reached stage 40.00) • ISO/DIS 10993-3Biological evaluation of medical devices Part 3: Evaluation of genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity (Draft – Reached stage 40.00) • ISO/DIS 10524-3Pressure regulators for use with medical gases Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (Draft – Reached stage 40.00) • ISO 13485:2016Medical devices — Quality management systems — Requirements for regulatory purposes (Reached stage 90.20)

Annex 2: FDA Draft Guidance

	Draft Guidance(s):
List of documents:	• Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations • Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations • Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency

Annex 3: TGA

	Proposal:
List of documents:	• N/A

Annex 4: Health Canada

	Draft Guidance(s):
List of documents:	• N/A

Annex 5: EU

	Draft Guidance(s):
List of documents:	• N/A

Annex 6: IMDRF

	News:
List of documents:	• Good machine learning practice for medical device development: Guiding principles • Characterization Considerations for Medical Device Software and Software-Specific Risk