GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 69 **Version Number:** 3 **Date of next review:** December 2026

Medical Devices and Equipment Management Policy

Policy Statement

It is the policy of Public Health Wales that all practicable steps should be taken to ensure all risks associated with the acquisition, management and use of medical devices are minimised to protect the public health and safeguard the interest of service users, carers and staff.

According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception

This policy also applies to in vitro diagnostic (IVD) medical devices, such as the equipment, reagents and software that is utilised by the microbiology and screening laboratories which, in the main, do not come into direct contact with patients but may nevertheless cause indirect harm to patients if they do not perform as intended.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality, and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA) Managing Medical Devices Guidance and adherence to Gov.UK guidance for in vitro medical devices:

- In vitro diagnostic medical devices procurement safety quality and performance
- In vitro diagnostic point of care test devices

Software and Stand-alone apps can also be defined as Medical Devices under certain circumstances and the applicability of Medical Device Regulations must be considered when in-house software applications are developed or procured in

support of our services, (e.g. within Screening Services). Further guidance can be found at:
Medical devices: software applications (apps) - GOV.UK (www.gov.uk)
MHRA Software flowchart (publishing.service.gov.uk)

It is the responsibility of the organisation and all employees to contribute to the provision of safe and secure use of all medical devices for service users, carers and staff.
The aim is to ensure whenever a medical device is used, it should be:

(a) Suitable for its intended purpose;
(b) Properly understood by the user;
(c) Maintained in a safe and reliable condition;
(d) Stored and disposed of appropriately;
(e) Decontaminated in accordance with manufacturers guidance.

Policy Commitment

To provide a clear understanding of the organisation's principles regarding the management of medical devices and to set out standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in Public Health Wales.

The aim of this policy is to support staff in understanding their responsibilities in relation to the management of medical devices. The knowledge and skills of staff, carers and services users have major implications for safety. Instructions must be clear, concise, and readily available. Training should be timely and effective and include procedures for the routine maintenance of medical devices by staff, carers, and service users.

The aim of the policy is to ensure that there are arrangements in place to ensure that medical device life cycles are appropriately governed and monitored. Where a medical device is outsourced, the lead for the use of the medical device must ensure that it complies with this policy. Medical device leads must ensure that equipment deployment, tracking and utilisation is monitored.

The policy aims to ensure that where a new medical device is acquired, relevant stakeholders are engaged in a discussion about their appropriateness and use.

Use of Medical Equipment for Non-designated Purpose; It should be noted that modification of equipment or use of any equipment for other than its intended purpose is a clear breach of the terms of the manufacturer's warranty. If a service user, carer or staff suffers harm in the process, the liability will not fall to the manufacturer.

Where a modification confers benefit, a fully documented risk assessment should be undertaken and risk management process defined before seeking approval from the MDMG.

Where a medical device is being deployed as part of a pre-UKCA-CE-CE UKNI marking clinical investigation, it must be approved by the Medical Devices Management Group.

This policy is based on statutory requirements produced by the Health and Safety Commission, Department of Health, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including the:

- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2008 and 2012
- The Medical Devices (Amendment) (EU Exit) Regulations 2021
- Health and Safety at Work etc. Act 1974
- Electricity at Work Regulations 1989
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

Supporting Procedures and Written Control Documents

All corporate policies and procedures are available on the Public Health Wales website

Other related documents are:

- Medical Devices and Equipment Management Procedure
- Health and Safety Policy
- Incident Management Policy
- Radiation Safety Policy
- Risk Management Policy
- Waste Management Policy
- Infection Prevention Control Policy
- Decontamination of Medical Devices and Equipment Policy & Procedure
- Disposal of Obsolete and Surplus Equipment Procedure
- Alerts, Safety Notices and Other Guidance Policy

Scope

This policy applies to all medical devices used in Public Health Wales, associated establishments, or supplied to service users for use in their own homes irrespective of whether the equipment has been purchased, loaned, or received as a gift. The purpose of medical device management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

This policy applies to all staff (employed or contracted) who use, repair, or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this policy and are familiar with other associated guidance.

All staff are expected to understand and implement the decontamination requirements of each medical device in their service. The 'Decontamination of Medical Devices and Equipment Policy and Procedure', local departmental Standard Operating Procedures and the Manufacturer's Instructions for Use should be referred to for detailed guidance on this.	
Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
Approved by	Quality, Safety and Improvement Committee
Approval Date	13 December 2023
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Group with authority to approve supporting procedures	Leadership Team
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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date by contacting the document author or the Board Business Unit.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	01/04/15	01/10/09	01/10/09	First version of policy.
2	01/02/18	27/11/18	05/12/18	Review undertaken in February/March 2018. Changes made as a result of legislative changes. Documentation currently subject to internal approval processes.
3	07/06/23 – 20/09/23	13/12/23	04/01/24	Review undertaken in April 2023 of the policy's alignment to MHRA guidance. Change to Executive Director and author.

				Statements added about outsourcing, deployment, acquisition, modification and change of use and pre-UKCA/CE/CE UKNI marking. Links to Supporting Procedures updated and MHRA Guidance link added. Decontamination Policy renamed due to ongoing development and consultation. Changes approved at MDMG on 7 June 2023. Use of Medical Equipment for Non-designated Purpose – text updated in line with MHRA guidelines. Reference to decontamination updated in line with 'Decontamination of Medical Devices and Equipment Policy and Procedure'. Inclusion of references to in vitro devices and software following comments received during consultation period.