Medicines & Healthcare products Regulatory Agency

Guidance on regulatory classification of point-of-use hospital water filters in the UK

The MHRA position on the appropriate classification of point-of-use water filters for the UK market, and advice for suppliers and procurers of these products

Scope

This guidance covers “point-of-use” (POU) water filters which are intended to be fitted to various access points for tap water in the healthcare environment, such as faucets and showerheads, to reduce bacterial contamination of the tap water that may occur as the water passes through the water pipelines. The filtered water produced may then be used for multiple purposes.

This may include general purposes such as drinking water or water for personal hygiene. Filtered water may also be provided in areas treating vulnerable patients who may be more at risk of bacterial infection, for example in burn wards, oncology units and NICUs.

Classification of hospital water filters for the UK market

The MHRA do not consider POU water filters to be medical devices, nor are they considered to be accessories of medical devices.

This was discussed at EU level in 2018. The competent authorities of the EU Member States, which included the UK at the time, reached a consensus that these products should be regarded as general hospital equipment and not medical devices. The MHRA has maintained this position since 2018.

The outcome of this discussion is recorded in the “Manual of Decisions” on borderline and classification of medical devices.

The MHRA therefore do not consider POU water filters to fall under the scope of UK or EU medical device legislation for the purposes of the UK market.

If you intend to supply or procure these products

Suppliers and procurers alike should be aware that the MHRA do not consider these products to fall under the legislation for medical devices. This means that filters intended for the UK market should not carry the UKCA mark, CE UKNI mark or CE mark to indicate compliance with UK or EU medical device legislation.

These markings of conformity should only be applied to products which fall under the scope of one of the product areas for which the UKCA/CE UKNI/CE mark is required, and which fully comply with the applicable legal requirements.

Please refer to this guidance for a list of product areas which require UKCA marking.

Since these filters should not carry the UKCA, CE UKNI or CE mark, the use of one of these markings does not automatically indicate a superior product, and may in fact indicate that the marking has been incorrectly affixed.

Procurers of POU water filters should review the full available product information to determine which particular POU filter is most suitable for your establishment's needs, irrespective of UKCA/CE UKNI/CE marking status.

Suppliers of these products may wish to contact their local Trading Standards for further regulatory advice.

Products incorrectly marketed as medical devices

Where the manufacturer has affixed the UKCA/CE UKNI/CE mark to a product to indicate compliance with medical device legislation, but the product does not meet the definition of a medical device, the product may be subject to compliance action according to Regulation 51 of the UK Medical Devices Regulations 2002 (as amended).

Every allegation of non-compliance is assessed using a risk-based system. Manufacturers are encouraged to bring themselves into compliance with the regulations. The MHRA possesses investigatory and enforcement powers which can be utilised should the circumstances warrant it.

Further information

The MHRA have stated this position on POU water filters in our updated guidance on borderlines with medical devices and other products in Great Britain.

For general enquiries on regulation of medical devices, contact devices.regulatory@mhra.gov.uk.