



Home Health & Monitoring Devices: evidence guidance

Version 1.0 | 13 October 2026

Prepare the evidence for a home health & monitoring devices entry. This guide covers the product details, reports and use information reviewers need.

Name the model and configuration

Identify the device, accessories, consumables and software needed for the claimed function. For a kit, explain which parts are essential and which configurations were assessed.

Provide model-specific performance material

Supply relevant reports with their methods, ranges and conditions. Explain calibration, environmental limits and uncertainty where relevant. A demonstration shows how a device operates; it does not replace performance evidence.

Show how home users complete important tasks

Describe setup, operation, interpretation, cleaning and storage. Explain foreseeable errors, the instructions or design features addressing them, and when professional help is required. Include current warnings, maintenance arrangements, product responsibility and applicable market documentation. Implanted and life-support systems are outside this edition.

Evidence checklist

Area	Required material	Check before submitting
Configuration	Model, accessories, consumables, power and software	Tested configurations cover the entry.
Performance	Reports, ranges, conditions and relevant limitations	Unsuitable readings and uncertainty are explained.
Home use	Critical tasks, user evidence and instructions	Intended users were considered, not only professional operators.
Maintenance	Cleaning, calibration, replacement and storage	Users can recognise faults and obtain support.
Supply and risk	Relevant market records, quality material and concerns	Restrictions or recalls affecting the model are disclosed.

Explaining configuration differences

If a report concerns a trained operator with one accessory, explain the evidence for an entry intended for untrained users with a different accessory. State where maintenance or environmental conditions affect performance, and make the same conditions visible in the instructions.



Map claims to sources

For each principal claim, record its exact wording, report or study, file and page, assessed version, method or population, finding and limitation. Identify the author and relevant relationship with the applicant. Explain how evidence about a different formulation, component or version applies to your product.

Prepare readable files

Supply readable reports, with the original and relevant English passages where needed. Keep private reports separate from proposed public information. Remove personal information not needed for review.

The entry permits up to 20 attachments and 250 MB in total: 25 MB per PDF and 10 MB per image. Video is supplied by link. Contact the awards team if an essential report exceeds these limits.

[Return to the category](#) · [Use the evidence worksheet](#) · [Read the rubric](#)