Medicines & Healthcare products Regulatory Agency

MHRA Health Institution Exemption survey

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is working to refine its policy and guidance on the Health Institution Exemption (HIE). The policy exempts certain devices that are manufactured, used or modified by a health institution for use within that health institution from meeting the requirements of the Medical Devices Regulations 2002 (MDR 2002).

The MHRA is inviting stakeholders in Great Britain (GB) to share information on how the health institution exemption (also referred to as an in-house manufacturing exemption) is currently being used in practice. We welcome your responses.

Please note, this survey is open to health institutions in GB. It will remain open until **11:59pm on Monday 15 September 2025** and should take about 15 - 20 minutes to complete.

Findings from this survey will inform policy options for reviewing the current position on the health institution exemption in GB. The survey is not a formal public consultation, and any subsequent review of the HIE will be subject to applicable consultation requirements.

For any questions relating to the completion of the survey, please email info@MHRA.gov.uk, with “Health Institution Exemption Survey” in the subject line.

Information for respondents

This survey is designed so you can skip questions and/or opt to answer only certain sections. You do not need to complete your response in one sitting. To resume the survey, click the same link and you will be able to come back to it at another time to finish it off.

Once you have completed the survey, please submit your response by **11:59pm on Monday 15 September 2025**.

Participants would benefit from having to hand information about medical devices manufactured and used under the Health Institution Exemption (HIE) (if any) within their organisation, such as:

- types of devices being manufactured under the HIE, and in which departments?
- information on the scale of use (e.g., does your organisation use the HIE to manufacture devices on an individual / small scale basis, or for larger volumes)?
- information on why your organisation uses the HIE (e.g., is it because patient needs are not met by commercially available devices etc)?
- information on how you monitor safety and performance of devices produced or modified under the HIE
- information on what guidance you are using in this area (e.g. does your organisation currently use MHRA guidance, or other sources)?

If you are responding on behalf of a health institution with more than one department, we encourage responses on behalf of the institution as a whole, as well as responses from specific departments, where possible. Please note we have included a definition of industrial scale in this survey which will be being kept under review.

Please note, this survey has been designed to show or hide certain sections and/or questions depending on your answers to previous questions.

Background

The Medical Devices Regulations 2002 (MDR 2002) do not define the terms ‘health institution’ or ‘health institution exemption’. Similarly, MHRA guidance on in-house manufacture of medical devices does not provide a definition of the health institution exemption. For the purpose of this survey, the **Health Institution Exemption (HIE)** is an exemption from the requirements of the MDR 2002 that applies to devices which are manufactured by health institutions and used only for their own patients, on the health institution’s premises or its immediate vicinity.

Data protection notice

This survey seeks the views of individuals to inform MHRA's understanding of the existing use of the in-house manufacture exemption from the Medical Devices Regulations 2002 (MDR 2002) requirements by health institutions.

This notice sets out how data collected through this survey will be used and respondents' rights under Articles 13 and/or 14 of the UK General Data Protection Regulation (GDPR). Further information can be found at Medicines and Healthcare products Regulatory Agency privacy notice - GOV.UK.

Data controller

The Medicines and Healthcare products Regulatory Agency (MHRA) is the data controller.

What personal data we collect

You can respond to this survey online. Alternatively, you can download the form, complete it and send this to us by email at info@mhra.gov.uk with the subject line "Health Institution Exemption survey".

We will collect data on:

- whether you are responding on behalf of a department and/or organisation
- what department and/or organisation you are responding on behalf of (if any)
- the name of your department and/or organisation
- the country and region your department and/or organisation provides services in the UK (if any)

With your consent, we will also collect data on:

- your email address (if completing a paper survey and submitting it by email, or if you have confirmed that the MHRA can contact you about your response); and
- any other personal data you volunteer by way of evidence or example in your response to open-ended questions in the survey; therefore, to remain anonymous, please refrain from disclosing any personally identifiable information in these questions.

How we use your data (purposes)

Your data will be treated in the strictest of confidence. We collect your personal data as part of the survey process:

- for statistical purposes, for example, to understand how representative the results are and whether views and experiences vary across demographics
- so that MHRA can contact you for further information about your response (if you have given your consent).

Legal basis for processing personal data

The legal basis for processing your personal data is to perform a task carried out in the public interest, or in the exercise of official authority vested in the controller.

Data processors and other recipients of personal data

All responses to the survey will be seen by:

- Professionals within MHRA who are working on this survey and policy area
- MHRA's third-party supplier (SocialOptic), who is responsible for running and hosting the online survey

No personally identifiable data will be shared.

MHRA may also share your responses, when anonymised, with Department of Health and Social Care, Government Legal Department, Office for Life Sciences, and any other government body identified to be part of this survey.

International data transfers and storage locations

Storage of data by the MHRA is provided via secure computing infrastructure on servers located in the UK. Our platforms are subject to extensive security protections and encryption measures. Storage of data by SurveyOptic is provided via secure servers located in the United Kingdom (UK).

Retention and disposal policy

Personal data will be held by the MHRA for 3 years and disposed of sooner if possible. SurveyOptic will securely erase the data held on their system 5 years after the online survey closes, or when instructed to do so by MHRA if the data has served its intended purpose (whichever happens earlier). Data retention will be reviewed on an annual basis. Anonymised data may be kept indefinitely.

How we keep your data secure

The MHRA uses appropriate technical, organisational and administrative security measures to protect any information we hold in our records from loss, misuse, unauthorised access, disclosure, alteration and destruction. We have written procedures and policies which are regularly audited and reviewed at a senior level. SurveyOptic is Cyber Essentials certified.

Your rights as a data subject

By law, you have rights as a data subject. Your rights under the UK General Data Protection Regulation and the UK Data Protection Act 2018 apply.

These rights are:

- the right to get copies of information – individuals have the right to ask for a copy of any information about them that is used
- the right to get information corrected – individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected;
- the right to limit how the information is used – individuals have the right to ask for any of the information held about them to be restricted, for example, if they think inaccurate information is being used;

- the right to object to the information being used – individuals can ask for any information held about them to not be used. However, this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case; and
- the right to get information deleted – this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case.

Comments or complaints

Anyone unhappy or wishing to complain about how personal data is used as part of this programme, should contact dataprotection@mhra.gov.uk in the first instance or write to:

Data Protection Officer

MHRA

10 South Colonnade

London

E14 4PU

Anyone who is still not satisfied can complain to the Information Commissioner's Office. Their website address is www.ico.org.uk and their postal address is:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Definitions

For the purpose of this survey, the following definitions apply:

- **Medical device** - A fuller definition of medical device is contained in Regulation 2 of the Medical Devices Regulations 2002 (MDR 2002). The term medical device encompasses a range of different types of devices used for the diagnosis, prevention, monitoring and treatment of disease, injury, or disability, including:

a. general medical devices
b. software as a medical device (including AI as a medical device)
c. implantable devices (including active implantable devices) – those medical devices intended to be totally or partially introduced into the human body and remain in the human body
d. system and procedure packs – combinations of products that are packaged together and intended to be used for a specific medical purpose
e. medical devices with a sterile aspect
f. invasive medical devices
g. non-invasive medical devices
h. devices that are composed of substances
i. devices that administer substances or medicines
j. devices for disinfecting/cleaning
k. in vitro diagnostic (IVD) devices - used for the in vitro (outside of a living organism) examination of specimens from the human body
l. accessory to a medical device - an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used

- **Adaptable devices** - Devices that are assembled at the point of use or adapted for individual patients (within the parameters for use of the device set out in the manufacturer's instructions for use) are not in scope of the HIE and not considered as custom-made devices. Examples of adaptable devices include assembling an orthopaedic implant, or adapting a prosthetic limb to a socket.
- **Aids for daily living** - Assistive technologies and living aids devices that may or may not be a medical device in scope of the MDR 2002. Whether they are in scope depends on the function (e.g., compensation for or alleviation of a disability) and intended purpose (medical or non-medical).
- **Custom-made devices** - Medical devices manufactured to a written prescription from a healthcare practitioner and intended for sole use by a particular patient. This includes moulded impressions. These devices are not in scope of the HIE if taken home by patient.
- **Health Institution (HI)** - For the purposes of this survey, the MHRA considers that a health institution is a body that's primary purpose is the care of patients and/or promotion of public health. Examples of bodies that qualify as health institutions are NHS trusts, the National Blood Authority, a dentist or GP practice as well as UK government organisations whose primary purpose is to support care and treatment or

patients and/or promote public health. The MHRA considers that private hospitals and bodies that provide private healthcare are health institutions, provided that the primary purpose of those bodies is the care of patients and/or promotion of public health.

- **Industrial scale** - For the purpose of this survey, this term is interpreted to mean: the mass production or operation of medical devices, typically using machinery, automation, and standardised/repeatable processes. It implies that the activity is being carried out at a volume or intensity suitable for commercial or mass-market purposes, rather than for personal, or small-scale use to a targeted population.
- **In-house device** - A medical device manufactured within a health institution or modified outside the parameters for use of the device set in manufacturer's instructions for use. The device is only used within the premises or immediate vicinity of the legal entity that manufactured it.
- **Legal entity** - For the purpose of this survey, the MHRA view is that a health institution will be a single legal entity (for example, a Trust or Health Board, rather than an individual hospital) although there may be exceptional circumstances where it is appropriate to treat two different legal entities as a single health institution. This comes from MHRA's current guidance on the HIE found here - In vitro diagnostic medical devices: guidance on legislation - GOV.UK. There is no legal definition of a legal entity in the MDR 2002.
- **Modifying a device** - For the purpose of this survey, where an action is not explicit in a manufacturer's intended purpose or instructions for use, modifying a device could include:

1. significant deviations from the instructions for use that alter the function, performance or purpose of the device,
2. using an existing device for a purpose not intended by the manufacturer,
3. modifying a device for a new purpose
4. or the use of sample types, accessories or components or combining devices not specified by the manufacturer.

- **Off-label use** - Use of a medical device for a purpose not covered in the manufacturer's instructions for use.
- **Reusable devices** - For the purposes of this survey, reusable devices refer to devices that can be sterilised and re-used under the manufacturer's instructions for use.
- **Single use** - The expression 'single-use' means that the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

Section 1: About your organisation

1. Which best applies to you?

- ○ I am responding as an individual
- ○ I am responding on behalf of an organisation

2. What sector do you operate in? Please select all that apply.

- ☐ Private healthcare services
- ☐ Public healthcare services
- ☐ Local authority
- ☐ UK Government
- ☐ Devolved Government
- ☐ Public body
- ☐ Medical laboratory services
- ☐ Non-medical/General testing laboratory services
- ☐ Other

3. Please select the region you/your organisation is located in.

- ○ England
- ○ Scotland
- ○ Wales
- ○ Other

4. If you are responding on behalf of an organisation, what is the legal entity name of your organisation? (optional)

5. If you are responding on behalf of an organisation, what region does your organisation provide services or goods in (if any)? Please select all that apply if you have multiple locations.

- [ ] England
- [ ] Scotland
- [ ] Wales
- [ ] Other

6. If you are responding on behalf of an organisation, what type of organisation do you represent? Please select all that apply.

- [ ] NHS England
- [ ] NHS Scotland
- [ ] NHS Wales
- [ ] NHS service providers
- [ ] NHS Trusts and foundation trusts or Integrated Care Boards (ICBs)
- [ ] NHS Board
- [ ] GP practice and other primary care organisations
- [ ] Dental practice
- [ ] Private and voluntary sector providers
- [ ] Regional body
- [ ] Local Authority
- [ ] Other

7. If you are responding on behalf of an organisation, do you represent one or more health institution (s) (as defined in this survey)?

- ( ) Yes
- ( ) No

8. If you represent a health institution(s), please specify the name of any Trust/Health Board or Local Authority are you part of (if any). (optional)

9. If you are part of a department within a health institution, what is the name of your department (if any)? (optional)

10. If you are part of a department within a health institution, what are the primary functions of your department? (optional)

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11. Would you be happy for us to contact you to follow up on your responses or address any further questions?

- ○ Yes
- ○ No

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12. Please provide your email address. With your consent we shall use the email address provided to follow up on your responses or address any further questions, if necessary. (optional)

Section 2: The scope of the health institution exemption (HIE) use (who, what & where)

We would like to understand the types of entities that are manufacturing and using devices under the health institution exemption (HIE) for medical devices in GB (again, also known as the ‘in-house exemption’), and the types and volumes of devices being manufactured and used in this way.

13. Do you currently use the health institution exemption for the manufacture of any medical devices in GB (including general medical devices and IVD devices)?

- ◯ Yes
- ◯ No

If you do not currently use the health institution exemption.

14. Please explain the main reason(s) why your organisation is not using the HIE? Please select all the apply.

- [ ] Commercial alternatives are available
- [ ] Economic reasons, such as a cost saving with using commercially available devices
- [ ] Lack of clarity on the requirements for using the HIE
- [ ] Lack of clarity on the scope for use of the HIE
- [ ] The HIE does not apply to our devices (e.g. devices are taken home, or transferred outside of the premises of the trust etc.)
- [ ] We were not aware of the HIE before this survey
- [ ] Other

15. What types of devices are you manufacturing under the HIE? Please select all that apply.

- [ ] General medical devices (excluding software and implantable devices)
- [ ] Active implantable medical devices (therapeutic/diagnostic/administering)
- [ ] Software medical devices (including AI as a medical device)
- [ ] Implantable medical devices
- [ ] Medical devices with a measuring function
- [ ] Medical devices with a sterile aspect
- [ ] Invasive medical devices
- [ ] Non-invasive medical devices
- [ ] Devices that are composed of substances
- [ ] Devices that administer substances or medicines
- [ ] Devices for disinfecting/cleaning
- [ ] IVD devices
- [ ] Systems and procedure packs
- [ ] Accessory to a medical device
- [ ] Don't know
- [ ] Other

16. Please give examples of the types of medical devices you manufacture under the health institution exemption.

17. How would you best describe the most common type of medical device that you manufacture under the HIE? Please select all that apply.

- [ ] General medical devices (excluding software and implantable devices)
- [ ] Active implantable medical devices (therapeutic/diagnostic/administering)
- [ ] Software medical devices (including AI as a medical device)
- [ ] Implantable medical devices
- [ ] Medical devices with a measuring function
- [ ] Medical devices with a sterile aspect
- [ ] Invasive medical devices
- [ ] Non-invasive medical devices
- [ ] Devices that are composed of substances
- [ ] Devices that administer substances or medicines
- [ ] Devices for disinfecting/cleaning
- [ ] IVD devices

- [ ] Systems and procedure packs
- [ ] Accessory to a medical device
- [ ] Dont know
- [ ] Other

18. For devices that you manufacture under the HIE, who requests their manufacture? Please select all that apply.

- [ ] University/ other academic institution
- [ ] Charitable organisations
- [ ] Healthcare professionals within your organisation
- [ ] Healthcare professionals outside your organisation
- [ ] Members of the public
- [ ] Family members/ care team
- [ ] Patient(s)
- [ ] Local Authority
- [ ] Other

19. What is your estimated total number of medical devices you manufacture under the HIE in GB each year?

- ( ) Less than 20
- ( ) Between 21 - 100
- ( ) Between 101 - 500
- ( ) Between 501 - 1000
- ( ) More than 1000
- ( ) Don’t know / Not able to quantify

20. Do you produce different types of devices under the HIE? In this question ‘type’ refers to a specific example of a medical device instead of a broader devices category (e.g. a drip stand would be a type of device, rather than ‘general medical device’ being a type of medical device for the purpose of this question).

- ( ) Yes
- ( ) No
- ( ) Don't Know

21. How many different types of devices do you provide under the HIE? In this question ‘type’ refers to a specific example of a medical device instead of a broader devices category (e.g. a drip stand would be a type of device, rather than ‘general medical device’ being a type of medical device for the purpose of this question).

- [ ] Only 1
- [ ] Between 2 - 5
- [ ] Between 6 - 10
- [ ] Between 11 – 20
- [ ] Between 21 - 50
- [ ] More than 50
- [ ] Don’t know / Not able to quantify

22. Do you produce the same volume of devices for each type of device you manufacture under the HIE?

- ( ) Yes
- ( ) No
- ( ) Don't Know

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23. Please could you select all the different volumes of devices you make for each type of device you manufacture under the HIE each year. For example, if you produce 5 of device A per year and approx. 150 of device B per year, please select both ranges (e.g. ‘Less than 20’ and ‘Between 101 – 500’).

- [ ] Less than 20
- [ ] Between 21 - 100
- [ ] Between 101 - 500
- [ ] Between 501 - 1000
- [ ] More than 1000
- [ ] Don’t know / Not able to quantify

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24. Do you consider that your organisation and/ or department produces any devices under the HIE on an industrial scale (as that term is defined in the definitions section of this survey)?

- ( ) Yes
- ( ) No
- ( ) Don't know

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25. Please explain the types of devices you are producing at an industrial scale under the HIE and your reasoning for this.

26. Have you ever manufactured single-use medical devices under the HIE?

- ○ Yes
- ○ No
- ○ Don't know

27. Please provide examples of single-use medical devices you manufacture under the HIE. (optional)

28. Have you ever manufactured reusable devices under the HIE?

- ○ Yes
- ○ No
- ○ Don't know

29. Please provide examples of reusable devices you manufacture under the HIE. (optional)

30. Are all medical devices that you manufacture under the HIE (your ‘in-house devices’): a) manufactured and used within your health institution’s premises or its immediate vicinity and b) manufactured without the intention to transfer the device(s) to another legal entity (i.e. via a sale, loan, hire, lease, gift, or any other type of legal transfer)

- ○ Yes
- ○ No
- ○ Don't know

In-house device manufacture outside the health institution premises or its immediate vicinity

31. How many of the devices would you estimate per year, that you use the health exemption for, are manufactured outside of the premises of your health institution or its immediate vicinity?

- ○ Less than 20
- ○ Between 21 - 100
- ○ Between 101 - 500
- ○ Between 501 - 1000
- ○ Over 1000
- ○ None
- ○ Don't Know
- ○ Other

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32. What ‘other’ premises are your in-house devices manufactured in? Please select all that apply.

- ☐ Another health institution's premise or vicinity
- ☐ Other

In-house device available/used off the health institution premises/vicinity

33. Are any devices you manufacture under the HIE, subsequently used outside of your health institution’s premises without full conformance to UK MDR requirements?

- ○ Yes
- ○ No
- ○ Don't Know
- ○ Prefer not to say

34. On average per year how many devices in total does this apply to?

- ○ Less than 20
- ○ Between 21 - 100
- ○ Between 101 - 500
- ○ Between 501 - 1000
- ○ Over 1000
- ○ None
- ○ Don’t know

35. Other than on your own health institution’s premises, where are these devices used? Please select all that apply.

- ☐ Patient's home
- ☐ Another health institution's premise or vicinity
- ☐ Other

In-house device transfer to another entity

36. Do you manufacture medical devices and transfer them to another entity (via a sale, loan, hire, lease, gift, or any other type of legal transfer). This could be, for example, to another hospital or care provider.

- ○ Yes
- ○ No
- ○ Don't know

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37. How many of the devices you manufacture under the HIE are transferred to another entity (on average each year)? (optional)

- ○ Don’t know
- ○ None
- ○ Less than 20
- ○ Between 21 - 100
- ○ Between 101 - 500
- ○ Between 501 - 1000
- ○ Over 1000

38. Please give examples of the types of entities you transfer these medical devices to.

39. Please could you explain the main reason(s) why, or under what circumstances, your organisation is transferring or intending to transfer the medical devices you manufacture under the HIE to another entity. For example, are you transferring devices between a hospital(s) and specialist R&D laboratories?

Section 3: How the health institution exemption is used in practise

We would like to understand how health institutions use the HIE in practice.

40. Are you following a quality management system (QMS) when manufacturing devices under the health institution exemption?

- ○ Yes
- ○ No
- ○ Don't know

41. Do you hold a certificate for your QMS?

- ○ Yes
- ○ No
- ○ Don't know

42. What standard is it certified under. Please select any/all that apply.

- ☐ ISO 9001
- ☐ ISO 13485
- ☐ ISO 15189
- ☐ ISO 17025
- ☐ Other

43. Are you following any standard (but not certified against it). Please select any/all that apply.

- [ ] ISO 9001
- [ ] ISO 13485
- [ ] ISO 15189
- [ ] ISO 17025
- [ ] IEC 62304
- [ ] No
- [ ] Other

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44. Is your organisation accredited to the United Kingdom Accreditation Service (UKAS)?

- ○ Yes
- ○ No
- ○ Don’t know

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45. Which ISO standard are you accredited under? Please select any/all that apply.

- [ ] ISO 9001
- [ ] ISO 13485
- [ ] ISO 15189
- [ ] ISO 17025
- [ ] Other

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46. Is your organisation accredited to the International Accreditation Forum (IAF)?

- ○ Yes
- ○ No
- ○ Don’t know

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47. Which ISO standard are you accredited under? Please select any/all that apply.

- [ ] ISO 9001
- [ ] ISO 13485
- [ ] ISO 15189
- [ ] ISO 17025
- [ ] Other

48. Does your department keep records of the medical devices specifically manufactured by your department under the HIE?

- ( ) Yes - for all devices
- ( ) Yes - for some devices
- ( ) No
- ( ) Don't know

49. What records does your department keep of devices they manufacturer under the HIE?

- [ ] A register or log to capture records of devices manufactured under the HIE
- [ ] Users of the device
- [ ] Approvals for use records
- [ ] Technical documentation
- [ ] Incident reports
- [ ] Asset records on the organisation’s medical equipment inventory database
- [ ] Change management records
- [ ] Location of the device
- [ ] Other

50. Are you currently voluntarily complying with any UK medical device regulatory requirements in respect of medical devices you are producing under the HIE? Please select all that you comply with from the below list or use the 'other' option to indicate any activities not listed below.

- [ ] Produce a technical file for medical devices
- [ ] Meeting relevant standards or common specifications
- [ ] Meeting relevant essential requirements
- [ ] Registering medical devices with the MHRA
- [ ] Maintaining a post-market surveillance system to monitor device safety and performance and reporting device incidents and field safety corrective actions to the MHRA
- [ ] Other

51. How does your organisation oversee medical devices manufactured under the health institution exemption?

- ○ A certain team is responsible for management of medical devices manufactured under the health institution exemption with a common management system across the organisation
- ○ Multiple departments are manufacturing medical devices under the health institution exemption all under different systems
- ○ Other

52. Are there particular training and capabilities you consider important for those managing and overseeing medical devices manufactured and used within health institutions to have? Please specify all you consider important.

53. Before manufacturing devices under the health institution exemption, do you consider whether there are alternative devices available on the market?

- ○ Yes
- ○ No
- ○ Sometimes
- ○ Don't know

54. Please could you describe your process for checking if there are alternative devices available on the market?

55. Do you conduct ongoing surveillance of the market after a device has been manufactured and/or used under the health institution exemption to ensure that there are no commercially available alternatives?

- ○ Yes
- ○ No
- ○ Sometimes
- ○ Don’t know

Section 4: Reasons for using the health institution exemption in practice

We would like to understand the motivations for health institution's use of the HIE.

56. What are the main reason(s) why your organisation is manufacturing devices under the HIE?

- [ ] Meeting unmet clinical needs
- [ ] No commercial alternative
- [ ] There is a commercial alternative, but it doesn't perform to an appropriate standard
- [ ] Economic such as cost-saving
- [ ] Discontinuation or disruption of commercial product(s) from the market
- [ ] Other

We are interested to hear from health institutions about how the current HIE impacts on their organisation, including impacts on patients' access to appropriate devices. For each of the statements below, please could you indicate to what extent you agree/ disagree with the statement.

57. The HIE is important to ensure patients' access to medical devices treatments.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

58. The HIE is important to ensure patients' unmet clinical needs are met.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

59. The HIE is important to the commercial considerations of our organisation.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

60. The HIE is important to ensure patients' access to innovative medical technologies.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

61. Please expand on any of the statements above, or your motivations for using the HIE, including any positive or negative impacts it has for your organisation below (optional)

62. Do you encounter any barriers to, or issues with, your preferred use of the HIE?

- ○ Yes
- ○ No

63. Please explain the barriers/ issues you have encountered.

Section 5: HIE - Medical device safety and performance

We would like to understand better how devices manufactured under the HIE perform in terms of safety and performance.

64. Do you have any systems and/or processes in place to gather data on outcomes of use of medical devices manufactured under the health institution exemption?

- ◯ Yes
- ◯ No

65. Please summarise at a high level how medical devices manufactured under the health institution exemption are monitored?

66. Have you seen or been notified about any quality or safety issues with medical devices manufactured under the HIE?

- ◯ Yes
- ◯ No

67. Please provide a summary and/or examples of these quality or safety issues.

68. Are you aware of any other (non-safety or quality) problems having arisen with the manufacture of medical devices in your organisation under the HIE?

- ◯ Yes
- ◯ No

69. Please summarise or provide examples of any problem(s) you are aware of.

70. We are interested in whether your organisation reports any incidents occurring with devices manufactured under the HIE. Please select any of the below you report these to.

- [ ] MHRA Manufacturers Online Reporting Environment (MORE)
- [ ] MHRA Yellow Card Scheme
- [ ] We report this to our incident reporting system/ platform (e.g. Datix)
- [ ] We report this to a section of our organisation
- [ ] Other

Section 6: HIE - Current guidance and information

We would like to understand whether health institutions are aware of and use MHRA guidance on the HIE, and to identify opportunities to improve this guidance. For these questions the MHRA's In-house manufacture of medical devices in Great Britain guidance can be found here: https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices

71. Before completing this survey, were you aware of the MHRA's In-house manufacture of medical devices in Great Britain guidance?

- ○ Yes
- ○ No

72. Do you utilise the MHRA's In-house manufacture of medical devices in Great Britain guidance?

- ○ Yes
- ○ No

73. Do you find this guidance clear?

- ○ Yes
- ○ No

74. Please suggest details on how this guidance could be improved (e.g., particular areas for clarification, definitions, scenarios).

75. Do you utilise other sources of guidance on the HIE?

- ○ Yes
- ○ No

76. Please select all sources of guidance from the below list that you utilise (including guidance produced within your own organisation).

- [ ] IPEM Guidance
- [ ] RESMAG Guidance
- [ ] EU Guidance MDCG 2023-01
- [ ] EU MDR 2017/745 Art 5.5
- [ ] MHRA NI in-house manufacture guidance
- [ ] Other

Section 7: HIE use in clinical investigations

We would like to understand how health institutions may use the HIE in relation to in-house clinical investigations. For the purposes of this section, a ‘clinical investigation’ is a study using a medical device on or with patients, in controlled conditions, to determine if it is safe to use or performs as intended. This **does** include devices repurposed in-house for a new intended use, as well as those manufactured in-house from scratch. This only includes studies of medical devices which examine either the safety and performance of the in-house device (usability studies, research studies producing generalisable knowledge, etc. are not included here). Where a study examines both device safety or performance and other objectives, these are to be included. If you are involved in clinical investigations, please respond to the following questions.

77. Are any clinical investigations you are conducting within your health institution conducted under the HIE (conducted without having made an application to MHRA and received a Letter of No Objection)?

- ( ) Yes
- ( ) No
- ( ) Don't know

If yes (i.e. you are using the HIE as part of one or more clinical investigations), please answer the following:

78. For health institutions using the exemption, how many studies are you conducting under the exemption per year?

79. For these studies, who is the study sponsor?

80. Name of the health institutions involved.

81. Who was the manufacturer of the device and where was the device made? (e.g. in the same building/ hospital)

82. If, in any of these studies, you are repurposing a device for a new intended purpose, what is the involvement of the original manufacturer and what information do they share with you?

83. Are your HIE studies used in particular types of devices, or particular circumstances?

- ○ Yes
- ○ No
- ○ Don't know

84. Please provide us with detail on what these are.

85. In your view, how has the use of the HIE in clinical investigations changed over the past 5 years? Please select all that apply.

- ☐ Increased use
- ☐ Decreased used
- ☐ Other

Thank you for your time in completing this survey. If you have any questions, please contact info@mhra.gov.uk with the subject line "Health Institution Exemption survey".

The survey will close on Monday, 15 September 2025.