# Medical Technologies Evaluation Programme

# Notification form

* Please fill in this form and email it to medtech@nice.org.uk to notify NICE about a product with potential benefits for patients\* and the health and social care system. This is the first step to take if you would like NICE to consider developing NICE guidance or NICE advice on the product.
* Anyone can notify a product to NICE. Please complete the form as best you can, and leave any sections that you are unable to complete blank.
* Once you submit the form, a member of the team will contact you to discuss the product in more detail, provide informal feedback on the information provided, and let you know about NICE processes, the options available, and any next steps.
* The information provided in this form and during any initial discussions is confidential, and without obligation to NICE or the notifier.
* Submission of this form will not automatically trigger the development of NICE guidance or NICE advice.
* Some sections of this form contain drop down lists for you to choose from. These may not work correctly on tablets, smartphones or other devices. Please use a compatible device (such as a PC with Microsoft) or contact medtech@nice.org.uk to request an alternative format form.

# Your information

Anyone can notify a product to NICE. The person detailed here will be contacted by a member of the NICE team.

|  |  |
| --- | --- |
| Name |  |
| Role | Click here to choose an option |
| E-mail |  |
| Phone number |  | Date | Click here to enter a date. |

# General information

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| What is the name of the product? |  |
| What is the name of the manufacturer? |  |
| Are you notifying for NICE advice or NICE guidance? **NICE advice** involves a summary of the key evidence that is relevant to a technology. It is not considered by a committee and recommendations aren’t made. NICE advice on medical technologies is usually published as [medtech innovation briefings](https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-Advice/Medtech-innovation-briefings). **NICE guidance** involves an evaluation of the evidence that is relevant to the technology. It is considered by a committee and recommendations are made. NICE guidance on medical technologies is usually published as [medical technologies guidance](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance) or [diagnostics guidance](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance).  | Click here to choose an optionDevelopment of NICE advice does not preclude development of NICE guidance at a later stage. |
| What is the regulatory status of the product in the UK? If ‘Other’ (for example, in-house diagnostic test) please give further details. | Click here to choose an option |
| What date was the product regulated for use in the UK, or when is it planned to be regulated for use in the UK? | Click here to enter a date. |
| Is an evaluation of this product by a UK national organisation planned or in progress? For example:* National Institute for Health Research
* NICE
* National Screening Committee
* Health Protection Agency
* UK Genetics Testing Network

If yes, please give details | Evaluation by another UK national organisation does not stop NICE from considering the product. This information is used to assess when a NICE evaluation could take place, as it would be unhelpful for two UK national organisations to evaluate the technology at the same time. |
| When was the product made available to the UK health and social care system, or when is it planned to be launched?  | Click here to enter a date.  |
| Please state the names of all UK organisation(s) in which the product is being used. Please give contact details | This is used to assess how widely the technology is currently used. NICE may also approach some organisations to gather additional information. |

# The product

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| --- | --- |
| Please briefly describe the product, and attach the instructions for use when you submit this form. | Keep this brief. Please don’t copy the instructions for use because this can be attached as a supplement.  |
| Does using the product involve any of the following?* making a cut or a hole to gain access to the inside of the body, for example, when carrying out an operation or inserting a tube into a blood vessel
* gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body, for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth,
* using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light), for example, using a laser to treat eye problems.
 | This question is used to assess whether using the technology is associated with an interventional procedure. |
| What properties or features of the product make it innovative or a significant modification when compared with other technologies of its type? | Understanding how the product differs from others is important. |
| Have any patents been granted in relation to this product?  | Click here to choose an option. This refers to granted patents only. Patients filed or patents pending should not be included.  |
| Is this product associated with a procedure code or HRG code?  | Please provide the procedure or HRG code if known. If it isn’t associated with a code, or you don’t know the code please leave this section blank. |
| Please list the names of all technologies that are similar or equivalent to the notified product, how these differ from the notified product (in terms of their functionality), and if they are currently used or available in the UK health and social care system. |  |
| Are you aware of any NICE or other guidance that relates to the use of this product? If so, please list the guidance. |  |

# The condition or indication

|  |  |
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| What indication or population is the notified product for?  |  |
| Please state if the focus of the notification is on the same indication or population as above, or a specific subgroup. If there is more than one subgroup you may submit additional forms to cover each subgroup separately.  | NICE evaluate products for use in a specific indication or population, but some indications or populations have subgroups where the use of a product would produce different outcomes, involve different staff, be in different care pathways etc. In these instances, it may be relevant for a NICE output to focus on a specific subgroup.For example:* A non-invasive monitoring technology can be used for monitoring a range patients with long term conditions such as COPD and heart failure, but the notifier may choose to focus on the COPD subgroup because this is where most of the evidence to support the product benefits has been generated.
* A diagnostic test can be used for assessing a range of liver conditions, but the notifer may choose to focus on its use in people with hepatitis, because this test addresses a specific unmet need for this subgroup of patients, and may enable treatment to be better directed.
* A wound dressing can be used on any sort of wound, but the notifier may choose to focus on non-healing diabetic foot ulcers because simple wounds may be able to be adequately healed by existing technologies, and the costs of the new product would not justify use in simple wounds.

The NICE team can provide further advice about choice of subgroups for inclusion in a NICE output once this form has been completed. |
| Approximately how many people in the publically funded UK health and social care system (e.g. the NHS) would be eligible for care with the notified product each year? | Please estimate this as best you can.  |
| What is the current standard of care for most people with this indication, population or subgroup? | Please describe the care that most people in this indication, population or subgroup currently have. |
| What is the gold standard of care for most people with this indication, population or subgroup?  | Please describe what is currently recommended as the best care in related NICE or other guidance, if this is different from the above. |
| In what setting is the product intended to be used?  | This is the place where the product is used. For example: outpatient clinic, GP practice, operating theatre, person’s home; or, if it is a test, the sample is taken in primary care and the test is run in a laboratory. |
| Who is intended to administer the product?  | For example: doctor, nurse, physiotherapist; or if it is a test, the test is run in a laboratory, and the results are sent to and acted upon by a GP in primary care. |
| Would this product be used in addition to or to replace elements of standard care?  | Would the product be used to replace an existing technology, or would it be used alongside existing technologies? |
| What would need to change to allow the product to be used in the health or social care system?  | Would use of the product require changes to the way in which current services are organised or delivered? Are additional facilities or product required for the benefits to be realised? Does the product require staff training? |
| You may draw (or attach) a schematic or flow diagram of the current care pathway and the new care pathway using your product.  | Draw the schematic or flow chart here, or attach a separate document to this notification when you submit it to NICE.  |

# The potential benefits

Please describe the key benefits to patients\* and the health and social care system that may be associated with use of the product, in comparison to the current standard of care.

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| What are the key patient\* benefits in comparison to the current standard of care?  | Please use a brief bullet point list. For example:* more accurate or earlier diagnosis
* improved management
* higher patient satisfaction
* fewer complications
* treatment can be started or stopped earlier
 |
| What are the key health and social care system benefits in comparison to the current standard of care? | Please use a brief bullet point list. For example:* fewer staff
* lower grade of staff
* reduced length of stay
* change of setting from secondary to community care
 |

# The evidence

Please use the table below to state which of the potential benefits listed in section 5 are supported by evidence that is available now or is planned to be generated.

There are no thresholds for the quantity or quality of evidence needed. Each product and potential benefit is assessed on a case by case basis.

Any evidence generated in any country, including real-world data, audit, confidential and unpublished evidence is acceptable to be included. The NICE team can provide further advice about the evidence once this form has been completed.

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| **Potential benefit** | **What is the status of the evidence for this benefit?** | **For evidence that has been generated:** |
| **Was the product used to generate this evidence?**  | **What was the indication or population**  | **How was the evidence generated?** | **Please include a reference to the evidence (use hyperlinks if available)** |
| *e.g. more accurate diagnosis* | *Publically available* | *Yes, this product was used to generate this evidence* | *People with Crohn’s disease* | *Patients were the main group involved in the generation of this piece of evidence* | *Author(s), date, title of paper, name of journal, issue and page number* |
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You don’t need to list all of the benefits, just the main ones with evidence available or planned to be generated. If you want to list more please add them to a separate document that can be attached when you submit this form.

|  |  |
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| If further evidence is being generated or is planned to be generated, please add details of it here. Please don’t copy and paste protocols. These can be attached as a separate document if necessary.  | For example:Start dates, anticipated end dates, expected number of participants, key outcomes, trial number/identifier  |

# Sustainability

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| You may state any sustainability benefits associated with the product compared with the current standard of care.  | For example: * less energy usage
* less waste
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# Costs

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| What is the expected lifespan of the product? |  |
| If the product needs servicing or maintaining, please describe the frequency and costs. |  |
| Is using the product in a health or social care setting in England likely to be cost incurring, or cost saving overall, compared with the standard of care outlined in section 4? | Choose an item. |
| If the product is likely to be cost saving, please describe where the cost savings are likely to occur.  |  |
| What is the average cost for each treatment, patient, use or test associated with the **current standard of care**? Please estimate this as best you can, including a breakdown of costs including any consumables if possible.  |  |
| What is the average cost for each treatment, patient, use or test for **the notified product**? Please include a breakdown of costs including any consumables.  | An example of how to calculate the cost is as follows:Cost per test is £2.34 based on the following assumptions: * Cost of technology = £2400 (ex VAT)
* 3 years use, active for 40 weeks of the year, 3 days per week on 3 patients per day.
* 40 weeks x 3 years = 120 weeks
* 3 days per week x 120 weeks = 360 days
* 3 patients per day x 360 days = 1080 patients.
* Based on these assumptions £2400/1080 = £2.22 per test.
* Plus disposable bandage 30cm - £0.04 x 2 (one for each area) = £0.08
* Plus alcohol wipes - £0.02 each x 2 sensors = £0.04
 |
| Is the cost for each treatment, patient, use or test for **the notified product** stated above confidential?  | Click here to choose an option |

# Safety issues

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| Please describe potentially adverse events for people having care with this product, including any reported to a notified body or other regulatory authority, in the published literature, or known to you from other sources (please include references). Please indicate their likely frequency. |  |
| Please describe any particular risks or potentially adverse events that might affect the health and social care system, its staff or its facilities because of using the product. |  |

# Equality and diversity

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE’s duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others. For further information on how we work, please see the [NICE website](https://www.nice.org.uk/about).

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| Are there any equality issues related to using this product? |  |

# Value proposition

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| You may summarise the product’s value proposition here, and briefly describe anything from the proposition that is not covered in the sections above.  |  |

# Expert advisers

NICE may contact expert advisers and ask them to complete a questionnaire on the product. Expert advisors should work in publically-funded UK health and social care services (for example, the NHS), and ideally have experience of using the product in this setting. Experts working outside of publically-funded UK health and social care services are not usually eligible.

You may suggest up to 3 expert advisers for NICE to contact.

|  |
| --- |
| **Expert adviser 1** |
| Name:  |
| Job title:  |
| Employer:  |
| Email address:  |
| Professional or specialist society:  |
| **Expert adviser 2** |
| Name:  |
| Job title:  |
| Employer:  |
| Email address:  |
| Professional or specialist society:  |
| **Expert adviser 3** |
| Name:  |
| Job title:  |
| Employer:  |
| Email address:  |
| Professional or specialist society:  |

# Confidentiality agreement

All information submitted at this stage is confidential between the notifier, NICE, and expert advisors, all of whom are bound by confidentiality agreements.

All notifiers must read and complete the confidentiality agreement below.

1. We, [insert name of organisation] (the ‘**Organisation**’), acknowledge that information may be disclosed to us in relation to our participation in the work of the Institute which is confidential (‘**Confidential Information**’). Often this material will be commercially sensitive, or provided to the Institute on an academic-in-confidence basis (for example, research that has not yet been published). Confidential Information may include, but is not limited to:

	1. the fact that a technology has been notified to the programme and is being considered (pre selection)
	2. the Medical Technologies guidance overview document (pre publication)
	3. the Medical Technologies guidance consultation document (pre publication)
	4. the final Medical Technologies guidance document (pre publication)
	5. the Medical Technologies guidance draft scope
	6. information relating to the existence, content or outcome of confidential discussions.
2. Subject to paragraph 3 below, we undertake to the Institute that we shall:
	1. keep all Confidential Information strictly confidential and, except as expressly permitted under this agreement shall not disclose, use, copy in whole or in part or modify or adapt any Confidential Information in any way without the Institute's prior written consent which may be given or withheld in its absolute discretion
	2. not use any Confidential Information for any purpose other than participating in the work of the Institute
	3. limit access to any Confidential Information to such individuals within the Organisation as require access for the purpose set out in paragraph 2)(b) above
	4. procure that any individual within the Organisation with access to any Confidential Information complies with this agreement
	5. return all Confidential Information to the Institute on written demand, and
	6. in the event that the Institute authorises any disclosure of Confidential Information by the Organisation to a third party we shall procure that such third party complies with this agreement as if he were a party to it.
3. The undertakings set out in paragraph 2 above (the ‘**Undertakings**’) shall not apply to information which:
	1. is in the public domain otherwise than through a breach of any of the Undertakings or a breach of any other confidentiality obligation owed by any person to the Institute
	2. was lawfully within our possession before it was disclosed to us by the Institute, and neither the Organisation nor our alternative source of the information owed any confidentiality obligation to the Institute in respect of it
	3. is required to be disclosed by any court of competent jurisdiction or any government agency lawfully requesting the same provided that we use our best endeavours to notify the Institute in advance of such disclosure or
	4. is approved for release by prior written authorisation of the Institute.
4. The Institute acknowledges that if the Organisation is a public authority as defined by the Freedom of Information Act 2000 ("the Act") then the Organisation will have to deal with any request for the Confidential Information in accordance with the Act.
	1. The Institute considers that as it is careful only to undertake to keep information confidential where there is good reason to do so, any request for Confidential Information is likely to be exempt from disclosure under section 41 of the Act.
	2. If the Organisation receives a request under the Act for Confidential Information and its initial view is that the Confidential Information should be released then it shall:
* promptly notify the Institute of this fact, providing a copy of the request and of the information requested
* allow the Institute a period of five working days to make representations on how it considers the request should be responded to
* conscientiously consider those representations, and
* if it decides to release any Confidential Information, provide the Institute with a copy of that information and the covering letter sent to the applicant.
	1. If the Organisation decides not to release Confidential Information in response to a request, it shall notify the Institute if the requestor challenges that decision by appealing to the Information Commissioner or the Information Tribunal.
1. We acknowledge that:
	1. breach by the Organisation of any of the Undertakings could cause the Institute harm that is irreparable and that cannot be compensated by damages, and that in the event of any actual or threatened breach by the Organisation of any Undertaking the Institute shall be entitled to apply for and obtain (regardless of any rights the Institute may have to claim damages) an injunction or other equitable relief against the Organisation
	2. this agreement constitutes the entire agreement between the Organisation and the Institute relating to the Confidential Information
	3. any amendments to or waiver of any of the terms of this agreement must be set out in writing and signed on behalf of the Organisation and the Institute
	4. this agreement is governed by English law and subject to the exclusive jurisdiction of the English courts.

Please insert an electronic signature. Alternatively, please print this document and provide a handwritten signature. **A typed signature cannot be accepted**

Signature: [insert handwritten or electronic signature]

A duly authorised officer for and on behalf of: [insert organisation’s name]

Print Name: [insert name] Date: [insert date]

# Submitting the completed notification form

The completed notification form should be emailed to medtech@nice.org.uk.

Please include the following documents as attachments to your email, if relevant:

Completed Notification form [ ]

Confidentiality and agreement form [ ]

Copy of your CE marking certificate [ ]

Instructions for use (for the notified indication) [ ]

Any supplementary information [ ]

You must tick the following declaration regarding any supporting documentation:

I understand that if I have attached any publication or other information in support of this notification I have obtained the appropriate permission or paid the appropriate copyright fee to enable my organisation to share this publication or information with NICE. [ ]