#



# Non-standard medical device request form

This form must be completed for all new medical device which are not available through the standardised medical products guide. All new medical devices must receive approval through the **Physical Health and Medical Device Group** before being purchased. Once completed this form should be sent to the Trust Medical Devices Safety Officer at HNF-TR.mdso@nhs.net

|  |
| --- |
| Product information |
| Medical Device make and model |  |
| Manufacturer |  |
| Product Number/Code (if applicable) |  |
| Details of person making request |
| Name |  |
| Job title  |  |
| Team |  |
| Division |  |
| Device overview |
| What is the purpose of this devices? |  |
| What is the cost of each device? |  |
| Is the device single use? |  |
| How many devices are required? |  |
| Are there any on-going maintenance costs? |  |
| How will the cost for purchase and maintenance be covered? |  |
| Does the devices require any internal or external calibration or quality assurance checks? |  |
| Where will the device be used for example ward, patient’s own home, clinic? |  |
| Who is the end user? i.e. registered or unregistered practitioners, patient, family/carers. |  |
| What group of patients will benefit from this device? |  |
| What is currently used? |  |
| Does this device need direct access to the internet or trusts wireless network? |  |
| Does the device store patient information? |  |
| Risk assessment  |
| What risks are associated with this device?  |  |
| What are the risks of not having this piece of equipment in your clinical area/team? |  |
| Best practice  |
| Is there any evidence or guidance to support the use of this device for example NICE technical appraisal?  |  |
| Who is the subject/clinical expert and have they been consulted in respect of this proposal? |  |
| Training and competency |
| What training will be required in order that staff are skilled in its safe use and how will this be delivered?  |  |
| How will competency be assessed? |  |
| What staff will use this device? Registered or non-registered clinicians |  |
| Physical Health and Medical Devices Group use only |
| Has the group been reviewed the manufacturers product information/guidelines? |  |  |  |
| Have there been any safety alerts or field safety notices published on relation to this device? |  |  |  |
| Have any risks been identified?  |  |  |  |
| Does this device need direct access to the internet or trusts wireless network? | Y/N | Comments |
| Is consultation with IG required and has a DPIA been completed? | Y/N  | Date completed |
| Does this device require approval at the Information Governance Group? | Y/N  | Date completed |
| Does this device require review by the Clinical Safety Officer? | Y/N  | Date completed |
| Does this device require review and approval by the Digital Delivery Group? | Y/N  | Date completed |
| What are the on-going costs for maintenance? | Comments: |
| What are the manufacturers guidelines on cleaning and decontamination?Have IPC been consulted?  | Comments: |
| Has expert advice been sought in relation to this equipment request? | Comments:  |
| Physical Health and Medical Devices review and approval  |
| Date reviewed at PHMD |  |
| Decision of review  | Approved/Declined/Deferred |
| Rationale for decision |  |

Non-standard Medical Device request form V1.0 June 2022 (QPaS)