# Pre-Acquisition Questionnaire (PAQ Form)

The purpose of this Form is to provide information to an NHS organisation about a medical device(s) which the NHS organisation has already evaluated & selected to approve acquisition of a device(s) – whether by purchase, exchange, rental, lease, donation or other agreement. (Note: The term ‘Device’ as used here is as defined in the Medical Devices Regulations 2002 and includes equipment, systems and accessories. In the case of systems the requirements below apply both to the individual constituent Devices and the configured system as a whole). The form must be completed in full.

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| **PART I – General Information** | | |
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| **Section A - Product Identification** | |  |
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| **No.** | **Question** | **Manufacturer Response** |
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| A1.1 | UDI Device Identifier *e.g. GTIN 14-digit format, leading with zero(es) for GTIN-13/GTIN-12* | Click or tap here to enter text. |
| A1.2 | Device Description (GMDN Code & Term): | Click or tap here to enter text. |
| A1.3 | MHRA registration number | Click or tap here to enter text. |
| A1.4 | Make: | Click or tap here to enter text. |
| A1.5 | Model Name: | Click or tap here to enter text. |
| A1.6 | Manufacturer’s Product Code: | Click or tap here to enter text. |
| A1.7 | Manufacturer: | Click or tap here to enter text. |
| A1.8 | NHS eClass Code: | Click or tap here to enter text. |
| A1.9 | Place of Manufacture or GLN (Global Location Number): | Click or tap here to enter text. |
| A1.10 | UK Supplier/ Distributor Name: | Click or tap here to enter text. |
| A1.11 | UK Responsible Person (for non-UK manufacture): | Click or tap here to enter text. |

**Please tick what additional information has been attached to this PAQ:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Declaration/s of Conformity (B1.1.2) | | | | | | | | | |  |  | | Pre-use quality assurance requirement details (D3.1.2) | | | | | | | | | | | | | | | | | |  |
| UK Approved Body / EU Notified Body letter confirming the validity of certificates (B1.6.2) | | | | | | | | | |  |  | | User training details (D4.1.2) | | | | | | | | | | | | | | | | | |  |
| MHRA’s notice of ‘no objection’ (B2.1.3) | | | | | | | | | |  |  | | Technical training details (D4.2.2) | | | | | | | | | | | | | | | | | |  |
| Notification to the MHRA (B2.2.2) | | | | | | | | | |  |  | | Decontamination / reprocessing training details (D4.3.2) | | | | | | | | | | | | | | | | | |  |
| List of accessories for the device (C1.2.2) | | | | | | | | | |  |  | | Installation requirements (E1.1.2) | | | | | | | | | | | | | | | | | |  |
| List of compatible accessory suppliers (C1.2.4) | | | | | | | | | |  |  | | ICT infrastructure requirements E1.2.2) | | | | | | | | | | | | | | | | | |  |
| Safety notice details (C1.9.2) | | | | | | | | | |  |  | | Acceptance testing protocol (E1.3.1) | | | | | | | | | | | | | | | | | |  |
| Details of hazard/s and their management (C2.1.3) | | | | | | | | | |  |  | | Test equipment / tooling software for servicing (E3.1.2) | | | | | | | | | | | | | | | | | |  |
| End-of-life waste management details (C3.4) | | | | | | | | | |  |  | | Decontamination details (E5.1.3) | | | | | | | | | | | | | | | | | |  |
| Device brochure / technical specification (D1.1) | | | | | | | | | |  |  | | Decontamination equipment & materials (E5.4.2) | | | | | | | | | | | | | | | | | |  |
| User manual or instructions (D1.2) | | | | | | | | | |  |  | | Special post-processing Device storage requirement details (E5.4.4) | | | | | | | | | | | | | | | | | |  |
| Technical manual (D1.3) | | | | | | | | | |  |  | | Digital Technology Assessment Criteria form (F1.6) | | | | | | | | | | | | | | | | | |  |
| **Section B - Regulatory Compliance** | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
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| **No.** | **Question** | | | | | | | | | | | | | | | | **Manufacturer Response** | | | | | | | | | | | | | | |
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| **B1- Device Regulatory Compliance** | | | | | | | | | | | | | | | | |  | | | | | | | | | | |  | | | |
| B1.1.1 | Does the Device have a valid UKCA and/or CE-marking for its intended use? | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| B1.1.2 | Attach the relevant Declaration/s of Conformity. | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| B1.2.1 | Under which legislation has the Device been conformity assessed? | | | | | | | The UK Medical Devices Regulations 2002 | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| EU Medical Device Directive | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| EU In-Vitro Diagnostic Medical Devices Directive | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| EU Active Implantable Medical Devices Directive | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| EU Medical Devices Regulation | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| EU In-Vitro Diagnostic Medical Devices Regulation | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| Other | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| B1.2.2 | If other, please specify. | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| B1.2.3 | If a Medical Device, which EU classification? | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| B1.2.4 | If an In-Vitro Diagnostic Medical Device, which EU category? | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| B1.4.1 | Has this included UK Approved Body assessment? | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| B1.4.2 | If yes, provide UK Approved Body identification number and name: | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| B1.5.1 | Has this included EU Notified Body conformity assessment? | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| B1.5.2 | If yes, provide EU Notified Body identification number & name: | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| B1.6.1 | What is the expiry date for the Device’s certificate? | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | | | | | | | | | |
| B1.6.2 | If the certificate/s have expired or has an expiry date within the next 12-month period, attach the UK Approved Body/ EU Notified Body's letter confirming the continued validity of certificates | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
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| **B2- Non-Marked Devices** *(If not CE or UKCA marked)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |
| B2.1.1 | Is this a Medical Device for ‘Clinical Investigation’? | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
| B2.1.2 | If YES, quote the MHRA ‘no objection’ reference number: | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | |
| B2.1.3 | If YES, attach a copy of the MHRA’s notice of ‘no objection’. | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
| B2.2.1 | Is this an In-Vitro Diagnostic Medical Device for ‘Performance Evaluation’? | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
| B2.2.2 | If YES, attach a copy of notification to the MHRA. | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
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| **B3- Custom-Made Devices** | | | | | | | | | | | | | | | | |  | | | | | | | | | | |  | | | |
| B3.1.1 | Is this a ‘custom-made’ Medical Device? | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
| B3.1.2 | If YES, name the prescribing Medical Practitioner: | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| **B4-Other** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B4 | If NO to B2.1.1, and to B2.2.1 and to B3.1.1 provide justification of the Device’s status *(e.g.: MHRA-approved humanitarian grounds)* | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | |
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| **B5- Quality Management** | | | | | | | | | | | | | | | | |  | | | | | | | | | | |  | | | |
| B5.1.1 | Is the manufacturer currently certified to any management / quality system Standards? | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| B5.1.2 | If YES, which Standard/s & certification body? (*e.g., EN-ISO-9001, 13485, 14001, etc.)* | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
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| **Section C – Product Details** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **No.** | **Question** | | | | | | | | | | | | | | | | | **Manufacturer Response** | | | | | | | | | | | | | |
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| **C1- Product Details** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C1.1.1 | Are there special storage requirements? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.1.2 | If yes, specify | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.2.1 | Does the Device have accessories? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.2.2 | If YES, attach details of all accessories encompassed by the PAQ return for the device | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.2.3 | If YES, does the device offer compatibility with other suppliers' or manufacturers accessories? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.2.4 | If YES, attach a list of compatible suppliers for the accessories | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.3 | Is this Model a subcomponent of a system? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.3.1 | If YES, attach system details | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.4 | Identify the mobility of the Device: | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.5 | What is the Device warranty period and what is covered under Warranty? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| C1.6 | Is this an implantable Device? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.7 | When was this Model first placed upon the market? | | | | | | | | | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | |
| C1.8 | Confirm the manufacturer / supplier has a system for notification of Device alerts/ upgrades to a named hospital representative. | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.9.1 | List here any manufacturer Field Safety Notices, MHRA Device Safety Information, National Patient Safety Alerts or other form of safety communications that have affected the device. | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| C1.9.2 | Attach details including corrective actions, plans and status for all safety communications listed. | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
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| **C2- Hazards** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| C2.1.1 | Does the Device present particular hazards that require special safety management measures? *(e.g.: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)* | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| C2.1.2 | If YES, specify the nature of the hazard/s. | | | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| C2.1.3 | If YES, attach details of the hazard/s and the measures required for their management. | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
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| **C3- End of Life Commitment** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| C3.1.1 | What is the recommended working lifetime **or** number of uses for this Device? | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | |
| C3.1.2 | If working lifetime is measured in number of uses, how does the Device monitor the number of cycles it has been run for? | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | |
| C3.2.1 | Is this model likely to be superseded in the next 3 years? | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| C3.3 | To what date is manufacturer product support for this Model guaranteed? | | | | | | | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | | | |
| C3.3.1 | To what date is availability of all parts required to maintain this Model guaranteed? | | | | | | | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | | | |
| C3.3.2 | To what date is availability of all accessories / consumables guaranteed? | | | | | | | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | | | |
| C3.3.3 | To what date is the availability of maintenance and repair services guaranteed? | | | | | | | | | | | | | | | | | | | | | | Click or tap to enter a date. | | | | | | | | |
| C3.4 | Attach details for end-of-life waste management of the Device. | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
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| **Section D – Resources & Training** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **No.** | | | | | | | **Question** | | | | | | | | | | | **Manufacturer Response** | | | | | | | | | | | | | |
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| **D1- Resources** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| D1.1 | | | | | | Provide the URL to the device brochure/ technical specification.  *If no URL, confirm it is attached to form* | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | |
| D1.2 | | | | | | Provide the URL to the User Manual or instructions.  *If no URL, confirm it is attached to form* | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | |
| D1.3 | | | | | | Provide the URL to the Technical Manual.  *If no URL, confirm it is attached to form* | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | |
| D1.4 | | | | | | What support resources are available? *(e.g., e-learning, helpdesk, literature, website resources, etc)* | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
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| **D2- Loan Devices** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| D2.1.1 | | | | | | Is identical loan device normally available in the event of equipment failure or safety recall? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | |
| D2.1.2 | | | | | | If YES, what is the typical delivery time for loan equipment? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | |
| D2.2 | | | | | | Is loan equipment provided free of charge within warranty period? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | |
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| **D3- Pre-Use Procedures** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| D3.1.1 | | | Does the Device require periodic pre-use procedures to be undertaken by users? *(e.g., calibration, qualification, PoCT controls, etc.)* | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D3.1.2 | | | If YES, attach details of quality assurance requirements | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
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| **D4- Training** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| D4.1.1 | | Is competency-based user training available from the manufacturer or an authorised provider? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.1.2 | | If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))* | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.2.1 | | Is competency-based technical training (test, maintenance, repair) available from the manufacturer or an authorised provider? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.2.2 | | If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))* | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.3.1 | | Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.3.2 | | If YES, attach details *(details must include amount offered, duration, location, etc. (and costs, if any))* | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.4 | | Are qualification / competency records of training providers available upon request? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| D4.5 | | Is training available for the lifetime of the Device? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
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| **Section E – Technical Support** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **No.** | | | | | | | **Question** | | | | | | | | | | | **Manufacturer Response** | | | | | | | | | | | | | |
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| **E1- Installation** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| E1.1.1 | Does the Device have installation requirements and / or require ancillary services or other prerequisite arrangements? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.1.2 | If YES, attach detail. | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.2.1 | Does the Device have ICT/ infrastructure needs (such as Connecting to Image system and PAC/ HL7 connectivity requirements)? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.2.2 | If YES, attach detail. | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.3.1 | Has a protocol for post-delivery device inspection and acceptance testing been attached? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.3.2 | If NO, attach justification | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.3.3.1 | If YES, is any test equipment/ tooling required to carry out acceptance testing? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.3.3.2 | If YES, attach detail. | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E1.3.4 | If YES, is acceptance testing and setup of equipment carried out by the Manufacturer or Authorised Supplier? | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
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| **E2- Servicing and Maintenance** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| E2.1 | | | | | Is the device serviceable (as opposed to single-use disposable)? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| E2.2.1 | | | | | Does the manufacturer recommend scheduled testing and/ or preventative maintenance for this device? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| E2.2.2 | | | | | If YES, what is the recommended test/ maintenance interval? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| E2.2.3 | | | | | If NO, attach justification | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| E2.3 | | | | | Who is responsible for servicing/ maintenance? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| E2.4.1 | | | | | Is there a service centre? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| E2.4.2 | | | | | If YES, what support is available? *(e.g. return to base, send out engineer, site-based service)* | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
| E2.4.3 | | | | | If YES, in what country is the service centre located? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| E2.4.4 | | | | | If YES, what is the estimated timescale for faulty equipment repair or replacement (in weeks)? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
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| **E3- In-House Servicing** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| E3.1.1 | Does the manufacturer support in-house servicing by providing necessary tools, software and documentation? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E3.1.2 | If YES, attach details of test equipment / tooling / software required for equipment servicing. | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | |
| E3.1.3 | If YES, provide technical training details in D4.2.2 | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | |
| E3.1.4 | If YES, can repair instructions be provided (in electronic format)? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
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| **E4- Spare Parts** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| E4.1 | | | | Are parts, consumable and accessories stocked in the UK? | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| E4.2.1 | | | | Are spare parts for this device available for purchase? | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| E4.2.2 | | | | If YES, what are the average lead times for delivery (in weeks)? | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | |
| **E5 – Decontamination** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| E5.1.1 | What level of Device decontamination is required? | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | |
| E5.1.2 | For multi-component systems identify all applicable levels | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| E5.1.3 | Provide URL to decontamination details (or attach to form) | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| E5.2 | For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664? *NOTE: Decontamination instructions must meet the process parameters for the country they are being supplied for use in* | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.3 | Provide guidance on suitable (and non-suitable) cleaning products available in UK? | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| E5.4.1 | Does the Device require processing / reprocessing before / between uses? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.4.2 | If YES, attach decontamination process requirements for special equipment, tools and materials. | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.4.3 | If YES, are there any special post-processing Device storage requirements? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.4.4 | If YES, attach detail | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.5.1 | Is there a limit to the number of Device reprocessing cycles? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| E5.5.2 | If YES, what is the limit? | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
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| **Section F - Data Security** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
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| **No.** | **Question** | | | | | | | | | | | | | | | | | **Manufacturer Response** | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **F1- Data Security** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| F1.1 | All Devices that contain digital technology including any medical devices that fall into the category of Software as a Medical Device or AI as a Medical Device should be assessed against the Digital Technology Assessment Criteria in addition to completing this form, even if you are piloting or trailing it. If a developer has multiple products, each one should be assessed against DTAC.  You can locate the DTAC form at: <https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/>  Confirm you have attached this form where applicable. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| F1.2 | If your device has embedded software that falls outside of the DTAC does the device store or transmit patient information that will require information governance measures? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| F1.3 | Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| F1.4 | If your device has embedded software that falls outside of the DTAC are patches available to be supplied or applied to meet compliance as per DSPT protocols? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| F1.5 | Is the device intended to be used in a patient home connecting to WiFi, mobile data or mobile phone to record and transmit patient information? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| F1.6 | Does the device have the capability for remote support or software updates using a network connection? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| |  | | --- | | **DECLARATION:** | |  | | We agree that the NHS organisation will be entitled to rely upon the contents of this Form and its attachments, and that subsequent non-compliance with the statements contained herein will entitle the NHS organisation to seek redress. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Name:** | Click or tap here to enter text. | | |
| **Position:** | Click or tap here to enter text. | | |
| **Company:** | Click or tap here to enter text. | | |
| **Address:** | Click or tap here to enter text. | | |
| **Email** | Click or tap here to enter text. | **Telephone:** | Click or tap here to enter text. |
| **Website:** | Click or tap here to enter text. | **Ownership Detail:** | Choose an item. |
| **Signature:**  *Electronic signature acceptable* | A white square with a blue border  Description automatically generated/ Click or tap here to enter text. | | |
| **Date:** | Click or tap to enter a date. | | |

PART II – Transaction Details

Previous sections in PART I provided general information; this PART II addendum provides details specific to particular transaction/s for the supply of the product and should be completed by the device supplier (e.g. Manufacturer, Authorised Representative or other)

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| --- | --- | --- | --- | --- |
| **No.** | **Question** | | **Response** | |
| G1.1 | On what basis will the product be supplied, (including Devices for clinical investigation / research)? | | | Choose an item. |
| For supply by loan or donation, other than Devices for clinical investigation / research | | | | |
| 1.2.1 | Is the Supplier on the NHS Supply Chain Master Indemnity Agreement (MIA) Register? *(Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the NHSSC)* | | | Choose an item. |
| F1.2.2 | If YES, has a NHS Supply Chain (NHSSC) MIA Call-Off Agreement Form been attached? | | | Choose an item. |
| F1.2.3 | If YES, confirm NHSSC MIA registration number: | Click or tap here to enter text. | | |
| F1.2.4 | If NO, attach an Indemnity Insurance Certificate (for local indemnity agreement with the customer). | | | Choose an item. |
| F1.3 | For supply by loan or donation of Devices for clinical investigation / research, has confirmation of Health Research Authority (HRA) approval, including indemnity arrangements, been attached? | | | Choose an item. |
| F1.4.1 | Is the particular item to be supplied a pre-used product? | | | Choose an item. |
| F1.4.2 | If YES, attach the usage and full service history. | | | Choose an item. |
| F1.5.1 | Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product? | | | Choose an item. |
| F1.5.2 | If YES, attach the issued Notices / Alerts. | | | Choose an item. |

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| **Name:** | Click or tap here to enter text. | | |
| **Position:** | Click or tap here to enter text. | | |
| **Company:** | Click or tap here to enter text. | | |
| **Address:** | Click or tap here to enter text. | | |
| **Email** | Click or tap here to enter text. | **Telephone:** | Click or tap here to enter text. |
| **Signature:**  *Electronic signature acceptable* | A white square with a blue border  Description automatically generated/ Click or tap here to enter text. | | |
| **Date:** | Click or tap to enter a date. | | |