

PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure Medical Devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed; (questions for which the only available response is 'YES' indicate that this response is a requirement, if the question applies) - and that all supplementary information requested has been provided; (shaded boxes indicate that supplementary information is required).

Note: The term 'Device', as used here, includes equipment and systems; in the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole. (Accessories within the scope of the return need to be identified under 1(d).)

PART I

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier:		
Device Description: <small>(GMDN Code / Group if available)</small>		Weighing Scale
Type:	Make:	Marsden
	Model:	M-650
Manufacturer:		Marsden Weighing Machine Group Ltd
Supplier:		Marsden Weighing Machine Group Ltd
EU Authorised Representative:		Marsden Weighing Machine Group Ltd

- 1 a) When was this Model first placed upon the market ? 2014
- b) Is this Model still in production ? NO YES if NO, when did production cease ?
- c) Any outstanding Field Safety Corrective Actions / Field Safety Notices ? NO YES All issued Notices / Alerts attached to this return ? YES
- d) Does this return cover a range of Model variants ? NO YES If YES, list of Models attached to this return ? YES
- e) Does this return cover Accessories ? NO YES If YES, list of Accessories attached to this return ? YES
- f) Has a Device brochure and specification been attached to this return ? YES

REGULATORY COMPLIANCE:

- 2 a) Does the Device meet the Essential Requirements of all currently applicable EC Directives ? NO YES
- b) Which EC Directive/s apply ?
- Medical Devices Directive Classification? ← (1, 1-m, 1-s / IIa / IIb / III)
- Active Implantable Devices Directive
- In-Vitro Diagnostics Medical Device Directive Category? ← (general / self-test / List-A / List-B)
- Other/s
- which Directive/s? 2014/31/EU Non Automatic Weighing Instruments
- 3 a) Is the Device CE-Marked, for its intended use, to all currently applicable EC Directives ? NO YES
- b) - if YES, have the EC Declaration/s of Conformity been attached to this return ? YES
- 4 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device), then -
- a) Is this a Medical Device for 'Clinical Investigation' ? NO YES
- if YES, quote the MHRA 'no objection' reference
- if YES, has a copy of the MHRA's notice of 'no objection' been attached to this return ? YES
- b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ? NO YES
- if YES, has a copy of notification to MHRA been attached ? YES
- c) Is this a 'custom-made' Medical Device ? NO YES
- if YES, name the prescribing Medical Practitioner:
- d) - if NO to 3(a), and to 4(a) (b) and (c), then provide justification of the Device's status -
- Wheelchair Weigher
- 5 a) Which EC conformity assessment route/s have been adopted?
- full QA type examination product verification production QA
- product QA unit verification internal control (self declaration)
- b) Has this included Notified Body conformity assessment ? NO YES
- Notified Body identification number & name:
- c) Is the manufacturer currently certified to any management system Standards ? NO YES
- which Standard/s ? ISO9001:2015 / SGS & 2014/31/EU ← (eg: EN-ISO-9001, 13485, 14001, etc.)
- Certification Body: SGS

PRODUCT COMMITMENT:

- 6 a) To what date is product support for this Model guaranteed ? YES
- b) Does this include training; servicing, repair & availability of parts; supply of consumables / accessories ? YES
- c) What is the Device warranty period? Have warranty details been attached to this return ? YES
- d) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES
- e) What is the recommended working lifetime for this Device? ← (not applicable for disposable Devices)
- f) Have details for end-of-life waste management of the Device been attached to this return ? YES
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PRODUCT SUPPORT:

- 7 a) Can an additional User Manual be provided (electronic format) ? YES
- b) Can a Technical Manual be provided (electronic format) ? (Any cost for doing so should be included in the response to 9(a)) NO YES
- c) Is identical equipment normally available as free-of-charge loan in the event of equipment failure ? NO YES
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Commissioning & Deployment

- 8 a) Has a protocol for post-delivery acceptance testing of Device function and safety been attached to this return ? YES
- b) Does the Device have particular installation requirements and / or require ancillary services or other prerequisite arrangements ? NO YES
- if YES, then have details of all installation requirements been attached to this return ? YES
-

Technical Support

- 9 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service ? NO YES
- if YES, then have details of all service contract options been detailed, fully costed and attached to this return ? YES
- where is the servicing facility located ?
- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? YES
- are qualification / competency records of servicing staff available upon request ? YES
- b) Is the servicing organisation currently certified to any management system Standards ? NO YES
- which Standard/s ? ← (eg: EN-ISO-9001, 13485, 17025, etc.)
- Certification Body:
- c) Do the contract alternatives offered in 9(a) include an option for in-house equipment servicing by hospital staff ? NO YES
- if YES, have details of the availability of spare / replacement parts to support equipment servicing been attached to this return ? YES
- if YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this return ? YES
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Decontamination

- 10 a) What level of Device decontamination / reprocessing is required ?
 single-use cleaning disinfection sterilisation
- b) If not single-use, have validated decontamination protocol/s been attached to this return ? YES
- c) For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES
- d) Have all requirements for special reprocessing equipment, tools and materials been detailed in the attached information ? YES
- e) Have any special post-processing Device storage requirements been detailed in the attached information ? YES
- f) Is there a limit to the number of Device reprocessing cycles ? NO YES If YES, what is the limit ?
- g) Are Devices uniquely identifiable ? NO YES
- h) Is this an implantable Device ? NO YES
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Data Security

- 11 a) Does the Device store or transmit patient information that will require information governance measures ? NO YES
- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return ? YES
- b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems ? NO YES
- if YES, then have details of Device IT software / hardware compatibility requirements been attached to this return ? YES
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this return ? YES
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Particular Requirements

- 12 a) Does the Device present particular hazards that require special safety management measures ? NO YES
(eg: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)
- identified hazards:
- if YES, then have details of the nature of identified hazards been attached to this return ? YES
- b) Does the Device require particular performance quality assurance measures ? (eg: calibration, qualification, PoCT controls, etc.) NO YES
- QA measures:
- if YES, then have details of quality assurance requirements been attached to this return ? YES
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IMPLEMENTATION SUPPORT:

- 13 a) Is competency-based user training available from the manufacturer or an authorised provider ? NO YES
 - if YES, have details of user training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES
- b) Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider ? NO YES
 - if YES, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES
- c) Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider ? NO YES
 - if YES, have details of decontamination training offered (amount / content / assessment / duration / location / cost / etc.) been attached ? YES
- d) Are qualification / competency records of training providers available upon request ? YES
- e) If other additional support facilities are available, (eg: helpdesk, literature, website resources, etc.), have details of these been attached ? YES

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes in the Form above) accompanies this return.

- | | | |
|---|--|--|
| 1.c) All issued Field Safety Notices / Alerts | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 1.d) List of all Model variants covered by this return | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 1.e) List of all Accessories covered by this return | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 1.f) Device brochure / specification | ATTACHED <input checked="" type="checkbox"/> | |
| 3.b) EC Declaration/s of Conformity | ATTACHED <input type="checkbox"/> | |
| 4.a) MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation' | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 4.b) Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation' | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 6.c) Warranty details | ATTACHED <input checked="" type="checkbox"/> | |
| 6.f) Details for end-of-life waste management of the Device | ATTACHED <input type="checkbox"/> | |
| 8.a) Protocol for post-delivery Device acceptance testing | ATTACHED <input type="checkbox"/> | |
| 8.b) Details of installation requirements | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 9.a) Service support contract options for maintenance / repair | ATTACHED <input type="checkbox"/> | |
| 9.c) Availability of spare / replacement parts | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| Information / test equipment / tooling / software required for Device servicing | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 10.b) Validated decontamination protocol/s | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 10.d) Requirements for special reprocessing equipment, tools and materials | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 10.e) Details of special post-processing Device storage requirements | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 11.a) Details of patient information capture / encryption / storage / transmission / deletion | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 11.b) Details of Device IT software / hardware compatibility requirements | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| Details of provisions made for Device IT cybersecurity | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 12.a) Details of particular hazards that require special safety management | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 12.b) Details of particular performance quality assurance measures required | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 13.a) Details of user training offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 13.b) Details of technical training offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 13.c) Details of decontamination training offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 13.e) Details of any additional support facilities offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |

When reference is made to this Form and its attachments within the process of obtaining the specified product/s, we agree that the purchaser will be entitled to rely upon the contents and that subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:	Donna Jebson		
Position:	Sales Manager		
Company:	Marsden Weighing Group		
Address:	Unit 1 Genesis Business Park. Sheffield Rd. Rotherham. South Yorkshire. S60 1DX.		
Website:	www.marsden-weighing.co.uk		
Email:	sales@marsdengroup.co.uk	Telephone:	01709 364296
Signature:	D. Jebson	Date:	01/01/2021

PART II

for completion by the device Supplier
(eg: Manufacturer, Authorised Representative or other)

Previous sections in PART I provided for general Device information; this PART II addendum provides details specific to particular transaction/s for supply of the product:-

TRANSACTIONAL:

- 14 a) On what basis will the product be supplied, (including Devices for clinical investigation / research) ?
purchase ? exchange ? rental/lease ? loan ? donation ?
- b) For supply by loan or donation, other than Devices for clinical investigation / research -
Has a Department of Health (DH) MIA Call-Off Agreement Form been attached ? YES
Is the Supplier on the DH Master Indemnity Agreement (MIA) Register ? * NO YES
- if YES, then quote DH MIA registration number:
- if NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ? YES
(* Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the DH)
- c) For supply by loan or donation of Devices for clinical investigation / research -
Has confirmation of Health Research Authority (HRA) indemnity approval been attached ? YES
- d) Is the particular item to be supplied a pre-used product ? NO YES
- if YES, has usage and full service history been attached with this return ? YES

Name:	D. Jebson		
Position:	Sales Manager		
Company:	Marsden Weighing Group		
Address:	Unit 1 Genesis Business Park. Sheffield Rd. Rotherham. S60 1DX		
Signature:	D. Jebson	Date:	01/01/2021