

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 and that all supplementary information requested has been provided, (shaded boxes indicate that supplementary information is required); questions for which the only available response is 'YES' indicate that this response is a requirement, if the question applies.

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 this Form need to be identified under 1(d).)

PART I - PRODUCT INFORMATION

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier: (GS1-GTIN)		
Device Description: <small>(GMDN Code / Group if available)</small>		Weighing Scale
Type:	Make:	Marsden
	Model:	M-510
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 ? 2013
- b) Is this Model still in production ? NO YES if NO, when did production cease ?
- c) Does this Form cover a range of Model variants ? NO YES If YES, list of Models attached to this Form ? YES
- d) Does this Form cover Accessories ? NO YES If YES, list of Accessories attached to this Form ? YES
- e) Has a Device brochure and specification been attached to this Form ? 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 | <input type="checkbox"/> | Classification? | | <small>← (1, 1-m, 1-s / IIa / IIb / III)</small> |
| Active Implantable Devices Directive | <input type="checkbox"/> | Category? | | <small>← (general / self-test / List-A / List-B)</small> |
| In-Vitro Diagnostics Medical Device Directive | <input type="checkbox"/> | | | |
| Other/s | <input checked="" type="checkbox"/> | | | |
- 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 Form ? 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 Form ? 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 (e.g.: MHRA-approved humanitarian grounds)-
- Weighing Scale
- 5 a) Which EC conformity assessment route/s have been adopted?
- | | | | |
|-------------------------------------|---|--|--|
| <input type="checkbox"/> full QA | <input checked="" type="checkbox"/> type examination | <input checked="" type="checkbox"/> product verification | <input type="checkbox"/> production QA |
| <input type="checkbox"/> product QA | <input checked="" type="checkbox"/> unit verification | <input type="checkbox"/> internal control (self declaration) | |
- b) Has this included Notified Body conformity assessment ? NO YES
- Notified Body identification number & name: SGS IS09001
- c) Is the manufacturer currently certified to any management system Standards ? NO YES
- which Standard/s ? IS09001:2015 / 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 Form ? 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 Form ? YES

PRODUCT SUPPORT:

- 7 a) Can an additional User Manual be provided (electronic format) ? YES
- b) Can a Technical Manual be provided (electronic format) ? NO YES
- c) Is identical loan equipment normally available in the event of equipment failure ? NO YES
- (Any conditions or costs associated with 7(b) or 7(c) should be included in the response to 9(a))

Commissioning & Deployment

- 8 a) Has a protocol for post-delivery acceptance testing of Device function and safety been attached to this Form ? 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 Form ? YES

Technical Support

- 9 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair and support service ? NO YES
- if YES, then have details of all service contract options been detailed, fully costed and attached to this Form ? 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 Form ? YES
- if YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this Form ? YES

Decontamination

- 10 a) What level of Device decontamination is required ? - (for multi-component systems identify all applicable levels)
- none cleaning disinfection sterilisation
- b) If answer is not 'none', have validated decontamination protocol/s been attached to this Form ? YES
- c) For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES
- d) Have all decontamination process requirements for special 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 ↑ state if 'Single-Use'
- h) Is this an implantable Device ? NO YES

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 Form ? 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 Form ? YES
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this Form ? YES

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 Form ? 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 Form ? YES

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 Form.

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

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 Machine Group Ltd		
Address:	Unit 1, Genesis Business Park, Sheffield Road, Rotherham, S60 1DX		
Website:	www.marsden-weighing.co.uk		
Email:	sales@marsdengroup.co.uk	Telephone:	01709 364296
Signature:	D.Jebson	Date:	01/01/2021

PAQ Form (Part-I) - Ref. No.:

PART II – TRANSACTION DETAILS

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

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

PRODUCT INFORMATION:

This statement is to be read in conjunction with product information provided in **PAQ FORM (Part-I)** Reference No.:

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 to this Form ? YES
- 15 a) Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product? NO YES
 - if YES, are issued Notices / Alerts attached to this Form ? YES

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Email:	sales@marsdengroup.co.uk	Telephone:	01709 364296
Signature:	D. Jebson	Date:	01/01/2021