Department of Health & Social Care

NHS

The PAQ is endorsed by NHS Business Services Authority (NHSBSA), NHS Supply Chain (NHSSC), Health Care Supply Association (HCSA), Association of British Healthcare Industries (ABHI), and Association of Healthcare Technology Providers for Imaging, Radiotherapy & Care (AXREM).

PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this Form is to provide information to a NHS organisation about a Medical Device(s) which the NHS organisation shall then use to inform its pre-acquisition planning and approval of proposals to procure such Medical Device(s) – whether by purchase, exchange, rental, lease, loan, donation or other agreement. (Note: The term 'Device' as used here includes equipment, systems and accessories. 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).)

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.

PART I - PRODUCT INFORMATION

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier: (GS1-GTIN)		MAGW200
Device Description: (GMDN Code / Group if available)		12276 Handheld Woods Light
Type:	Make:	DARAY Limited
	Model:	MAGW200
Manufacturer:		DARAY Limited
Supplier:		**DARAY Limited**
EU Authorised Representative:		**Manfacturer**

1 a) When was this Model first placed upon the market ? **September 2021**

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) 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 ☒

c) Which EC Directive/s apply ?

Medical Devices Directive ☒ Classification? Class 1 ← (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?

c) Has this included Notified Body conformity assessment ? NO ☐ YES ☐

- Notified Body identification number & name:

d) Is the manufacturer currently certified to any management / quality system Standards ? NO ☐ YES ☒

- which Standard/s ? **ISO9001:2015 & ISO13485:2016** ← (eg: EN-ISO-9001, 13485, 14001, etc.)

- Certification Body: SGS UK Limited

3 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 2(a), and to 3(a) (b) and (c), then provide justification of the Device's status (e.g.: MHRA-approved humanitarian grounds)-

PRODUCT COMMITMENT:

4 a) To what date is manufacturer support for this Model guaranteed ? **3 years**
- does this include availability of parts and supply of consumables / accessories ? YES ☐
- does this include product support, as detailed below, (training, maintenance, repair, etc.) ? YES ☐

b) What is the Device warranty period? **3 years** Have warranty details been attached to this Form ? YES ☒

c) What is the recommended working lifetime for this Device? ← ('not applicable' for disposable Devices)

d) Have details for end-of-life waste management of the Device been attached to this Form ? YES ☐

e) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES ☐

PRODUCT SUPPORT:

5 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 5(b) or 5(c) should be included in the response to 7(b))

Commissioning & Deployment

6 a) Has a protocol for post-delivery inspection and 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

7 a) Is this a disposable non-serviceable device ? (- if YES, proceed to Section 8) YES ☒

b) Does the manufacturer or an authorised servicing agent provide a maintenance / repair and technical 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 ? **DARAY Ltd, Edison House, Robian Way, Swadlincote, Derbyshire, DE11 9DH**
- 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 ☒

c) Is the servicing organisation currently certified to any management system Standards ? NO ☐ YES ☒
- which Standard/s ? **ISO9001:2015 & ISO13845:2016** ← (eg: EN-ISO-9001, 13485, 17025, etc.)
- Certification Body: **SGS UK Ltd**

d) Do the contract alternatives offered in 7(b) 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

8 a) What level of Device decontamination is required ? - (for multi-component systems identify all applicable levels)

☐ none ☒ cleaning ☐ disinfection ☐ sterilisation

- if answer is not 'none', have validated decontamination instructions been attached to this Form? YES ☒
- for sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES ☐

b) Does the device require processing / reprocessing before / between uses ? NO ☒ YES ☐
- if YES, have all decontamination process requirements for special equipment, tools and materials been detailed in attached information ? YES ☐
- if YES, have any special post-processing Device storage requirements been detailed in the attached information ? YES ☐
- is there a limit to the number of Device reprocessing cycles ? NO ☒ YES ☐ if YES, what is the limit ?
- are Devices uniquely identifiable ? NO ☐ YES ☒ ↑ state if 'Single-Use'
- is this an implantable Device ? NO ☒ YES ☐

Data Security

9 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

10 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:

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

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.

Name:	Maisie Leach		
Position:	Quality & Compliance Manager		
Company:	DARAY Limited		
Address:	Edison House, Robian Way, Swadlincote, Derbyshire, DE11 9DH		
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Email:	maisie.leach@daray.co.uk	Telephone:	01283 228 565
Signature:	M Leach	Date:	**22/09/2021**

PAQ Form (Part-I) – Declaration Reference No.:

PART II – TRANSACTION DETAILS

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

Previous sections in PART I provided 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)** Declaration Reference No.: _____
Dated: _____

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 -
Is the Supplier on the Department of Health & Social Care (DHSC) Master Indemnity Agreement (MIA) Register ? NO ☐ YES ☒
(Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the DHSC)
- if YES, has a Department of Health & Social Care (DHSC) MIA Call-Off Agreement Form been attached ? YES ☐
DHSC MIA registration number: **DHMIA1096/16**
- if NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ? YES ☐

c) 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 ? 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 ☐

Name:	Maisie Leach		
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