



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: <small>(GS1-GTIN)</small>		Not yet available	
Device Description: <small>(GMDN Code / Group if available)</small>		13187	Pulp Tester
Type:	Make:	Pulppen (trademark name)	
	Model:	Pulp Tester B1000 Analogue, Pulp Tester DP2000 DIGITAL	
Manufacturer:		Dental Electronic A/S, Metalbuen 38, 2750 Ballerup, Denmark	
Supplier:		Same as above	
EU Authorised Representative:		Mr. Jesper Lund	

- 1 a) When was this Model first placed upon the market ? 1975
- 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 | <input checked="" type="checkbox"/> | Classification? | IIa | ← (1, 1-m, 1-s / IIa / IIb / III) |
| Active Implantable Devices Directive | <input type="checkbox"/> | | | |
| In-Vitro Diagnostics Medical Device Directive | <input type="checkbox"/> | Category? | | ← (general / self-test / List-A / List-B) |
| Other/s | <input type="checkbox"/> | | | |
- which Directive/s?
- c) Has this included Notified Body conformity assessment ? NO YES
- Notified Body identification number & name: 0494 SLG Prüf- und Zertifizierungs GmbH, Hartmannsdorf, Germany
- d) Is the manufacturer currently certified to any management / quality system Standards ? NO YES
- which Standard/s ? ← (eg: EN-ISO-9001, 13485, 14001, etc.)
- Certification Body:
- 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 ? YES
 - 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? 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 ?
 - 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 ? ← (eg: EN-ISO-9001, 13485, 17025, etc.)
 - Certification Body:
 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 <input checked="" type="checkbox"/> | NOT APPLICABLE <input type="checkbox"/> |
| 1.d) List of all Accessories covered by this Form | ATTACHED <input checked="" type="checkbox"/> | NOT APPLICABLE <input type="checkbox"/> |
| 1.e) Device brochure / specification | ATTACHED <input checked="" type="checkbox"/> | |
| 2.b) EC Declaration/s of Conformity | ATTACHED <input checked="" type="checkbox"/> | |
| 3.a) MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation' | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 3.b) Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation' | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 4.b) Warranty details | ATTACHED <input checked="" type="checkbox"/> | |
| 4.d) Details for end-of-life waste management of the Device | ATTACHED <input checked="" type="checkbox"/> | |
| 6.a) Protocol for post-delivery Device inspection / acceptance testing | ATTACHED <input checked="" type="checkbox"/> | |
| 6.b) Details of installation requirements | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 7.b) Service support contract options for maintenance / repair | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 7.d) Availability of spare / replacement parts | ATTACHED <input checked="" type="checkbox"/> | NOT APPLICABLE <input type="checkbox"/> |
| Information / test equipment / tooling / software required for Device servicing | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 8.a) Validated decontamination instructions / protocols | ATTACHED <input checked="" type="checkbox"/> | NOT APPLICABLE <input type="checkbox"/> |
| 8.b) Requirements for special reprocessing equipment, tools and materials | ATTACHED <input checked="" type="checkbox"/> | NOT APPLICABLE <input type="checkbox"/> |
| Details of special post-processing Device storage requirements | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 9.a) Details of patient information capture / encryption / storage / transmission / deletion | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 9.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"/> |
| 10.a) Details of particular hazards that require special safety management | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 10.b) Details of particular performance quality assurance measures required | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 11.a) Details of user training offered | ATTACHED <input type="checkbox"/> | |
| 11.b) Details of technical training offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 11.c) Details of decontamination training offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |
| 11.e) Details of any additional support facilities offered | ATTACHED <input type="checkbox"/> | NOT APPLICABLE <input checked="" type="checkbox"/> |

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:	Mr. Jesper Lund		
Position:	CEO		
Company:	Dental Electronic A/S		
Address:	Metalbuen 38, 2750 Ballerup, Denmark		
Website:	www.denlux.com		
Email:	denlux@denlux.com	Telephone:	+45 4465 0661
Signature:		Date:	23.04.2021

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:
 - 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

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Signature:		Date:	23 .04 .2021