HAAG-STREIT UK

Supplier Questionnaire (QA2)

For Internal Use Only			
Supplier analysis reference number:			
Risk assessment conclusion:			
Approval given	Yes	No	
Signed by (Name, Date, Signature):			

SECTION 1 – Introduction

We would like to add your Company onto our Approved Suppliers List, you are therefore required to complete this questionnaire as follows:-

Please answer these questions honestly, answering no to certain questions does not necessarily mean that your Company will be excluded from our list. The aim of this questionnaire is to allow us to determine your ability to fulfil our orders.

Please complete this form electronically or in block capitals and sign.

Section number	Required by
2,3,6	All companies
4	Manufacturers and/or distributers of medical devices only
5	Companies which hold no formal ISO certification (e.g. ISO 9001)

SECTION 2 - Company Information		
2.1	Company name	
2.2	Address	
2.3	Telephone number	
2.4	Fax number	
2.5	E-Mail	
2.6	Total number of employees	
2.7	DUNS Number	
2.8	Global Location Number(s) (GLN) *if applicable*	
2.9	Economic Operators Registration & Identification Number (EORI) *if applicable*	
2.10	Single Registration Number (SRN) *if applicable*	
2.11	Details of product and/or process to be supplied:	

SECTION 3 - Certification & Audits			
3.1	Does your Company maintain an approved quality management system? (e.g. ISO13485 / ISO 9001) **If yes**, attach copies of your certificates and scope of approval	Yes	No
3.2	Does your company maintain approval under the Medical Device Directive 93/42/EEC and/or Medical Device Regulations 2017/745 or regional equivalent? **If yes**, please provide copies of these certificates	Yes	No
3.3	If applicable, who is your authorised representative?		
3.4	Does your Company have a Labour Standards Assurance System (LSAS) policy (or a regional equivalent) or plans to implement one? **If yes**, please supply copies of any policies and procedures relating to LSAS.	Yes	No
3.4a	**If no**, please explain the reason for exemption:		
3.5	Does your Company comply with REACH legislation EC 1907/2006 or a regional equivalent? **If yes**, please supply Safety Data Sheets (SDS) for applicable products.	Yes	No
3.5a	**If no**, please explain the reason for exemption		
3.6	Does your device comply with RoHS2 in accordance with directive 2011/65/EU or a regional equivalent? **If yes**, please supply the declaration of conformity.	Yes	No
3.6a	**If no**, please explain why your company does not comply		
3.7	Does your Company comply with WEEE regulations in accordance with directive 2012/19/EU or a regional equivalent? **If yes**, please supply a copy of the Company procedure/policy.	Yes	No

3.7a	**If no**, please explain the reason for the exemption		
3.8	Are you in a position to accommodate unannounced audits?	Yes	No
3.8a	**If no**, do you have plans to be prepared for an unannounced audit?	Yes	No
3.9	It is permissible to declare up to 6 weeks in the year when audits are not to occur. If you have specific shut down times (e.g. Christmas), please indicate below		
3.10	Do you have a disaster recovery plan/contingency plan in case of any accidents/events?	Yes	No
3.10a	**If yes**, please give details		

SECTION 4 - Medical Devices (Please only complete if you manufacture and/or distribute medical devices)			
4.1	Do you manufacture and/or distribute Medical Devices?	Yes	No
4.2	Are they CE marked against the Medical Device Directive (93/42/EEC) or Medical Device Regulations (2017/745)? **If yes**, please provide CE certification, technical specification of product and declaration of conformity	Yes	No
4.3	Please indicate the class(es) of device(s) to be supplied		
4.4	Please provide details of the QA/RA representative within your company (Name, Job Title, Email, Telephone)		
4.5	Do you place medical devices on the market under your own name? **If yes**, please provide D of C's for relevant product	Yes	No
4.6	Have you registered your facility with the relevant competent authority (e.g. MHRA) **If yes**, which authority?	Yes	No
4.7	Have you appointed a UK Representative Person?	Yes	No

	If yes, please provide details and a copy of your agreement		
4.8	Is any of the manufacturing process outsourced? E.g. sterilization, packing, testing, moulding?	Yes	No
4.8a	**If yes**, give further details (Name and address of company and any supporting certification(s))		
4.9	Are there instruction manuals available for all of your Medical Devices?	Yes	No
4.9a	**If yes**, please state languages available		
4.10	Are your instruction manuals made available on your website?	Yes	No
4.11	Are you registered with GS1 and do you have any Global trade item numbers (GTIN) registered? If yes, please provide a list of your GTIN's	Yes	No

SECTION 5 - Internal Systems Review (Please complete if no formal ISO certification e.g. ISO 9001 held)			
5.1	Do you have plans to obtain 3rd party approval? e.g. ISO 13485 **If yes**, please give estimated date for approval: DD/MMM/YYYY	Yes	No
5.2	Please indicate number of staff with direct Quality Assurance/Control responsibilities		
5.3	Do you have a system for material traceability including batch records?	Yes	No
5.3a	**If yes**, please briefly describe below as well as indicating retention periods		
5.4	Do you have a documented procedure for reviewing customer's contracts?	Yes	No

	If no, are records kept of contract reviews? Yes No		
5.5	Are contract quality conditions passed onto your suppliers?	Yes	No
5.6	Do you monitor your suppliers/subcontractors to ensure that contract quality conditions are passed on and complied with?	Yes	No
5.7	Do you perform regular self-audits?	Yes	No
5.8	Please indicate the types of inspection/verification techniques used: First off Patrol Statistical process control Operator Own Final 100%		
5.9	Is measuring equipment that is used for product verification regularly calibrated?	Yes	No
5.10	Is the inspection authority independent from the production authority?	Yes	No
5.10a	**If no**, who verifies that the work complies with the order?		
5.11	Are rejects/concessions/production permits reviewed for trends? **If yes**, is corrective/preventative action taken to prevent re-occurrence? Yes No	Yes	No
5.12	Please briefly describe how customer specification and/or drawings are controlled:		
5.13	Are procedures in place to deal with customer complaints/returns? **If yes**, are corrective/preventative reviews held? Yes No	Yes	No

SECTION 6 - Final Sign off	
6.1	Is there any additional information which you believe would be of use to our organisation? If so, please give details below, or use additional sheets

If any changes are made to the provided company information, certification, product or service provided advance notice of 3 months must be given and change accepted before altering the supplied product or service.

Please sign below to confirm your acceptance of this statement.

Questionnaire completed by:

Name: _____

Position: _____

Signature: _____

Date: _____