

Supplier Self Disclosure

A.COMPANY DETAILS				
1.1	Company Name			
1.2	Company Group			
1.3	Address			
1.4	Contact Person	Name:	Telephone No.:	Email:
1.5	Management			
1.6	Marketing & Sales			
1.7	Purchasing			
1.8	Production			
1.9	Design & Development			
1.10	Quality Management			
1.11	Total Number of Employees:			
1.12	Number of Employees working in Production:			
1.13	Number of Employees working in Quality Assurance:			

B.QUESTIONS ABOUT QUALITY MANAGEMENT			
2.1	Does your company have a quality management system certified by an accredited body?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.2	If yes, according to which standard, for example ISO 9001; ISO/TS 16949? (Please supply a copy of the certificate)	_____	
2.3	Does the quality manager directly report to the management of the company?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.4	Are internal audits held at regular intervals?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.4.1	▪ Are auditing procedures defined and documented?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.4.1	▪ Are records about the audits kept?	<input type="checkbox"/> yes	<input type="checkbox"/> no

C.QUALITY ASSURANCE			
3.1	Does your company have written regulations which ensure, <i>before</i> an order is processed, that the contractually agreed requirements or the relevant specifications can be fulfilled?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.2	Are quality checks performed?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.3	Are quality checks carried out by an independent department, for example Quality Control?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.4	At which stages are quality checks performed?		
3.4.1	▪ Receipt of goods	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.4.2	▪ During production	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.4.3	▪ Finishes goods after production	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.5	Do you follow written instructions for all quality checks?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.6	Do these instructions cover all relevant information about checking procedure, frequency, criteria and equipment?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.7	Are quality check results recorded and archived to enable backwards traceability of the orders?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.7.1	If yes, for how long are the records kept?	_____	
3.7.2	If yes, will you open these records to Olympus Soft Imaging Solutions GmbH?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.8	Is a documented procedure in place describing identification, routing and isolation of faulty products?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.9	Will Olympus Soft Imaging Solutions GmbH's approval be obtained <i>before</i> delivery of goods with design deviations?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.10	Will Olympus Soft Imaging Solutions GmbH be informed of defects that are, or may be, present in products, which have already been delivered?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.11	Will you notify Olympus Soft Imaging Solutions GmbH with a verified root cause analysis and a set of meaningful countermeasures at least 10 working days after a defect was discovered?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.12	Do you use a 5-Whys or similar analysis methodology when providing Olympus Soft Imaging Solutions GmbH with root causes analysis?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.13	Is there a system established for implementing and monitoring corrective measures and improvements?	<input type="checkbox"/> yes	<input type="checkbox"/> no

3.14	Do you have written instructions for complaints management?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.15	Is the management of test tools/equipment described in written instructions?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.16	Are the necessary test equipment and the test procedures available for performing the tests specified by the inspection instructions?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.17	Do you check the functioning of test equipment before using it?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.18	Do you regularly check the functionality/calibration of all the test tools/equipment in use?	<input type="checkbox"/> yes	<input type="checkbox"/> no

D. PRODUCTION MANAGEMENT

4.1	Are written instructions for the procedures in production available?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.2	Are the manufacturing procedures, production equipment and materials clearly defined?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.3	Are the critical parameters of the production process monitored?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.3.1	If yes, do you prepare and keep?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.4	Have you outsourced parts of the production to 3 rd party suppliers?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.5	Do you have an ERP system in place?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6	Are there written regulations in place on servicing and maintenance of the production facilities? (e.g. service plan, servicing instructions)	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.7	Are the production facilities regularly monitored and serviced?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.8	Are records of these servicing activities kept?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.9	Do you check your production facilities before use, if they are working correctly?	<input type="checkbox"/> yes	<input type="checkbox"/> no

E. PERSONNEL/TRAINING

5.1	Are there written definitions of the required qualifications of the personnel which has an impact on the quality of the product? (e.g. skill and qualification profiles, training plan)	<input type="checkbox"/> yes	<input type="checkbox"/> no
5.2	Are there written job induction or training schedules designed to ensure the employee's suitability for the job?	<input type="checkbox"/> yes	<input type="checkbox"/> no

5.3	Can you prove that the personnel has been properly trained in the production and testing processes as well as in the use of the tools?	<input type="checkbox"/> yes	<input type="checkbox"/> no
5.4	Does your company clearly define roles and responsibilities of the job positions that have an impact on the quality? (e.g. job description, qualification matrix)	<input type="checkbox"/> yes	<input type="checkbox"/> no

F. PROCUREMENT/LOGISTICS

6.1	Do you procure the required products according to clearly defined specifications?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.2	Is there a written procedure for supplier evaluation?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.3	Is there a system that enables traceability, monitoring of serial numbers and batch control of raw materials and end products?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.4	Are written packing instructions in place that define the packing process in terms of type of packaging, packaging material used and labelling?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.5	Are all products that have been approved for delivery stored under conditions that prevent mixing with products that have not been approved for delivery?	<input type="checkbox"/> yes	<input type="checkbox"/> no

G. CHANGE MANAGEMENT

7.1	Are written instructions in place that define the management of product changes with regards to functionality, size, materials, appearance, production process and documentation?	<input type="checkbox"/> yes	<input type="checkbox"/> no
7.2	Can you ensure to inform Olympus Soft Imaging Solutions GmbH of any change including changes in parts, materials, suppliers, logistics flow, location of production or processes before delivery?	<input type="checkbox"/> yes	<input type="checkbox"/> no

H. ENVIRONMENTAL MANAGEMENT

8.1	Does your company have an environmental management system certified by an accredited body?	<input type="checkbox"/> yes	<input type="checkbox"/> no
8.2	If yes, according to which standard, for example ISO 14001? (Please supply a copy of the certificate)	_____	

I. OTHER			
	If offered a contract, can the company accept the following conditions:		
9.1	▪ Signing of an agreement that defines quality assurance activities.	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.2	▪ Olympus Soft Imaging Solutions GmbH to perform audits to inspect whether the quality assurance measures defined meet the requirements	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.3	▪ To provide auditors with all design, production and quality documents and records requested during the audits	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.4	▪ To grant auditors access to the required facilities during the audits	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.5	▪ Possibility of preparing a long term supplier's declaration	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.6	▪ Possibility of creation of various declarations (CE, Reach, RoHs, etc.)	<input type="checkbox"/> yes	<input type="checkbox"/> no

This form was filled out by:	
Name	
Position	
Date	
Signature	

Please return the completed form to:	
By Email	osis.procurement@olympus-sis.com
By FAX	+49 (251) 79800-6489
By Post	Olympus Soft Imaging Solutions GmbH Procurement Department Coermühle 2 48157 Münster Deutschland