

Supplier self-disclosure

1. COMPANY DETAILS				
1.1	Company name			
1.2	Company Group			
1.3	Address			
1.4	Contact	Name:	Telephone no.:	Email:
1.5	Management			
1.6	Distribution/Sales			
1.7	Purchase			
1.8	Production			
1.9	Development/ Construction			
1.10	Quality			
1.11	Project management			
1.12	Total Number of Employees:			
1.13	Of which active in the field of production:			
1.14	Of which active in the field of quality assurance:			
1.15	Core competencies:			
1.16	General information about the product range:			

2. QUALITY			
2.1	Does your company have a quality management system certified by an accredited body?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.1.1	If so, on what basis of standards, e.g. ISO 9001; ISO 13485; IATF 16949? (Please enclose a copy of the certificate!)	_____	
2.2	Does the quality management officer report directly to the management?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.3	Are internal audits carried out at regular intervals?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.3.1	▪ Is the process defined and documented?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.3.2	▪ Are records created and kept?	<input type="checkbox"/> yes	<input type="checkbox"/> no
2.4	Are process FMEAs created?	<input type="checkbox"/> yes	<input type="checkbox"/> no

3. QUALITY ASSURANCE			
3.1	Are quality checks carried out? If so, at what time?		
3.1.1	▪ Goods Receipt	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.1.2	▪ Intermediate production check	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.1.3	▪ Final inspection	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.1.4	▪ Goods	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.2	Are the quality checks carried out by an independent department, e.g. quality control?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.3	Are there documented test instructions for all quality checks?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.4	Do these test instructions contain all the essential information about: test procedure; frequency of testing; test characteristics; Acceptance criterion; prescribed test equipment?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.5	Are the checks carried out logged and archived so that traceability to the order is possible?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.5.1	If so, how long will the test records be kept?	_____	
3.5.2	If so, are these test records available from Evident Technology Center Europe GmbH?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.6	Is there a written regulation for the identification, steering and isolation of defective products?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.7	Is Evident Technology Center Europe GmbH informed about	<input type="checkbox"/> yes	<input type="checkbox"/> no

	defects that affect or could affect goods that have already been delivered?		
3.8	Will Evident Technology Center Europe GmbH be informed within 14 working days of discovery of the error with a meaningful root cause analysis and a series of countermeasures (8D report)?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.9	Is a system established for the implementation and monitoring of corrective and improvement measures?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.10	Is there a work instruction for complaint management?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.11	Is there a written regulation for test equipment management?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.12	Is the capability of the test equipment you use checked before commissioning?	<input type="checkbox"/> yes	<input type="checkbox"/> no
3.13	Are all test equipment you use monitored according to plan?	<input type="checkbox"/> yes	<input type="checkbox"/> no

4. PRODUCTION			
4.1	Are there written assembly instructions for the activities and processes in production?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.2	Which manufacturing processes are established?		
4.3	Are manufacturing processes, production equipment and the material to be processed properly defined?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.4	Are the critical parameters of the production process monitored?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.4.1	If so, are there any records of this?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.4.2	If so, how long will they be kept?	_____	
4.5	Have they outsourced production processes to suppliers? If so, which ones?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.5.1	Are these suppliers ISO 9001:2015 certified?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6	Is an ERP system used? If so, for which areas?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6.1	▪ Storage	<input type="checkbox"/> yes	<input type="checkbox"/> no

4.6.2	▪ Production	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6.3	▪ Purchase	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6.4	▪ Quality control	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.6.5	▪ Production planning	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.7	Is there a written regulation for the maintenance and servicing of the production facility (e.g. maintenance plan, maintenance instructions, etc.)?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.8	Is there regular monitoring and maintenance of the production facilities?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.9	Are there any records of maintenance?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.10	Is the capability of the production facilities you use checked and logged before commissioning?	<input type="checkbox"/> yes	<input type="checkbox"/> no
4.11	Are production control plans (PLP) drawn up?	<input type="checkbox"/> yes	<input type="checkbox"/> no

5. PERSONNEL/TRAINING

5.1	Are there written specifications on the qualification, training and further education of the staff (e.g. qualification matrix)?	<input type="checkbox"/> yes	<input type="checkbox"/> no
5.2	Are there written training/induction plans regarding the requirements for the activity for the employees including associated evidence?	<input type="checkbox"/> yes	<input type="checkbox"/> no
5.3	Are the tasks and responsibilities of the individual positions defined in writing in your company (e.g. job descriptions)?	<input type="checkbox"/> yes	<input type="checkbox"/> no

6. PROCUREMENT/LOGISTICS

6.1	Do you procure required products according to a specification that contains all relevant property characteristics?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.2	Is there a documented procedure for supplier evaluation?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.3	Is a system established that controls the traceability and batch/serial number control of raw materials and end products?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.4	Are there written instructions for the packaging process in relation to, among others: type of packaging; packaging material; Marking?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.5	Are all products that are demonstrably released stored in such a way that mixing with non-approved products is excluded?	<input type="checkbox"/> yes	<input type="checkbox"/> no
6.6	Do you have experience with intra-European import / export?	<input type="checkbox"/> yes	<input type="checkbox"/> no

6.7	Do you have experience with non-European import/export?	<input type="checkbox"/> yes	<input type="checkbox"/> no
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G. DEVELOPMENT			
7.1	Are all development services carried out in-house? If not, which ones are solved externally?	<input type="checkbox"/> yes	<input type="checkbox"/> no
7.2	Do you use CAD systems? If so, which ones:	<input type="checkbox"/> yes	<input type="checkbox"/> no
7.3	Do you have your own patents? If so, for which products or processes:	<input type="checkbox"/> yes	<input type="checkbox"/> no
7.4	Which laboratory and test facilities are available in-house?		
7.5	Are product FMEAs created?	<input type="checkbox"/> yes	<input type="checkbox"/> no
7.6	Is there an own test or prototype construction? If so, which prototype facilities are used?	<input type="checkbox"/> yes	<input type="checkbox"/> no

H. PROJECT MANAGEMENT			
8.1	Do you have your own project management?	<input type="checkbox"/> yes	<input type="checkbox"/> no
8.2	Is a project plan created for requested products/projects?	<input type="checkbox"/> yes	<input type="checkbox"/> no

I. CHANGE MANAGEMENT			
9.1	Is there a written regulation to control product changes in terms of functionality, dimensions, material, appearance, production process and documentation?	<input type="checkbox"/> yes	<input type="checkbox"/> no
9.2	Is the approval obtained from the client before the implementation of a change?	<input type="checkbox"/> yes	<input type="checkbox"/> no

J. ENVIRONMENTAL

10.1	Does your company have an environmental management system certified by an accredited body?	<input type="checkbox"/> yes	<input type="checkbox"/> no
10.1.1	If so, according to which standard basis, e.g. ISO 14001? (Please enclose a copy of the certificate!)	_____	

K. OTHER

In the event of an order, is the Company prepared to accept the following conditions:

11.1	Signing of an agreement defining the quality assurance activities (quality assurance agreement).	<input type="checkbox"/> yes	<input type="checkbox"/> no
11.2	Submit documents/process flows on the effectiveness of the QM system and to ensure product quality for inspection as part of a supplier audit.	<input type="checkbox"/> yes	<input type="checkbox"/> no
11.3	To grant a representative of Evident Technology Center Europe GmbH access to the locations of the product development process.	<input type="checkbox"/> yes	<input type="checkbox"/> no
11.4	To grant the client of Evident Technology Center Europe GmbH access to the locations of the product development process.	<input type="checkbox"/> yes	<input type="checkbox"/> no
11.5	Signing of a long-term supplier declaration (LLE).	<input type="checkbox"/> yes	<input type="checkbox"/> no
11.6	Signing of declarations applicable to the product (e.g. CE, REACH, RoHS, etc.).	<input type="checkbox"/> yes	<input type="checkbox"/> no

L. REMARKS/ANNEXES

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This questionnaire was completed by:	
Name	
Function	
Date	
Signature	

Please send the completed questionnaire back to:	
By email	etce.procurement@evidentscientific.com
or by post	Evident Technology Center Europe GmbH Purchasing Department Johann-Krane-Weg 38 48149 Münster, Germany Germany