

# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE



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# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE

## 1 Supplier Name, Address

Company Name	SMT Schilling Metalltechnik GmbH
Company Address	Griesweg 33
Zip /Postal Code	78570
City	Muehlheim
Country	Germany
State /Province	Baden Wuerttemberg
Telephone	+49 7463 993090
Fax	+49 7463 99309 12
E-mail	<a href="mailto:info@smt-metalltechnik.de">info@smt-metalltechnik.de</a>
Website	<a href="http://www.smt-metalltechnik.de">www.smt-metalltechnik.de</a>
Tax Identification Number	DE180953077
Business opening times	Office: 08:00 to 12:00 and 13:00 to 16:30 Production: 06:00 to 12:00 and 12:30 to 22:00
Annual production shutdowns	Sommer holiday (August, 3 weeks) Christmas holiday (Dec- Jan 1-2 week (s))

## 2 Product and Manufacturing range

Product / Production Group	Description
Human Surgical Instruments	Instruments to hold, bend and cut Implants and wires Guide wires and as contract manufacture made special Instruments
Human Implants	Kirschner Wires and Steinmann Pins made as contract manufacture
Veterinary Instruments	Instruments for general orthopedic use
Veterinary Implants	Special Implants for knee surgery at dogs, Kirschner Wires and Steinmann Pins
Stainless Steel Tools	Stainless Steel Tools for use in clean rooms, Pharma, Electronic Industry, Food Industry, Sea and Offshore
Contract Manufacture	Products made due to customer specifications and drawings

To see our range of Products please visit our website:

[www.smt-metalltechnik.de](http://www.smt-metalltechnik.de)

## 3 Ownership

Ownership Structure	Private, owned
President / CEO/ Owner	Erik Schilling
Deputy CEO	Priska Schilling

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<b>Authorised representative</b>	Priska Schilling, Reiko Schilling
<b>Years at present facility</b>	Since 1996

## 4 Building Overview

<b>Facility size</b>	2500 Sq.m/22500Sq.ft
<b>Number of Facilities</b>	1
<b>Number of Buildings</b>	3 (Year 1996 / 2001 / 2017)
<b>Building Office, Show room, document storage</b>	970 Sq.m/8730Sq.ft
<b>Building Assembling, Cleaning, Packaging</b>	700 Sq.m/6300Sq.ft
<b>Building Production</b>	830 Sq.m/7470Sq.ft
<b>Ground total</b>	3750 Sq.m/33750Sq.ft
<b>Possible expansion</b>	500 Sq.m /4500 Sq.ft

## 5 Machine Park, Processes, Capability

### 5.1 Processes /Department

Raw material storage	Raw material Cutting	Raw material Annealing
Laser Cutting	Wire Cutting (EDM)	Sink EDM
Manual Drilling	Manual Milling	Manual Turning
Welding TIG (only for tools)	Pressing / Forming	Manual machine grinding
CNC Turning	CNC Milling	CNC K-Wire machining
Stone Tumbling	Grinding (Surface finishing)	Glas/Ceramic/Zirkonium Blasting
Assembling	In Process Cleaning	Final Cleaning
Laser Marking	In Process Inspection	Final Inspection
Packaging (non Sterile) conducted in a controlled room, with physical segregation from the remainder for the facility	Quality control	Storage
Purchasing	Financing	Design (R&D)

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## 5.2 Machine Park








Department	Machine	Qty	Capability	Picture
Milling	Haas Mini Mill	5	508x406x394	
Milling	Haas VF-2SS	1	762x406x508mm	
Milling	Haas VF-2TR	1	762x508x508	
Milling	Haas MDC 500	3	408x406x394	
Milling	Mazak VTC-20	1		
Milling	Mazak VTC 200	2		
Milling	Deckel FP 4A	1		
Turning	Mazak QT-8	1		

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Turning	Mazak QTN 200 MSY	1		
Material Cutting	Behringer HBP 220 A	1		
Material Cutting Wire EDM	AGIE EVOLution 3			
Material Cutting Lasercutting	HEL 100			
Material Pressing (Stamping)	WMW PYE 100	1		
Tumbling	Dreher VTS VT-FRE	1		
Tumbling	Rössler R155 EC	1		
Manual machine grinding	Blohm Simplex 11	1		
Blasting (Glass/Ceramic/Zirconium)	SIGG TR110DK	1		
Blasting (Glass/Ceramic/Zirconium)	SIGG TR70	1		
Blasting (Glass/Ceramic/Zirconium)	SBC 420	1		

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Annealing	Borel	1		
Lasermarking	Trumpf Vector Mark	1		
Lasermarking	Electrox Raptor FLEX YZ	1		
Lasermarking	SISMA LWS	1	Coming soon	
Cleaning	SMT RoboClean	1		
K-Wire Production	SMT WPM3	10		
Others, Handling System	KUKA 364/15	2		
Others: Grinding	Rema Metabo			

## 6 Personal Overview, Contact

### 6.1 Management

Title	Name	Telephone	E-mail
<b>President / CEO / Owner</b>	Erik Schilling	+49 7463 99309 20	schilling@smt-metalltechnik.de
<b>Deputy CEO / Quality Management Representative</b>	Priska Schilling	+49 7463 99309 14	priska.schilling@smt-metalltechnik.de
<b>Authorised representative 1</b>	Priska Schilling	+49 7463 99309 14	priska.schilling@smt-metalltechnik.de
<b>Authorised representative 2</b>	Reiko Schilling	+49 7463 99309 23	reiko.schilling@smt-metalltechnik.de

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# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE

## 6.2 Quality Management

Title	Name	Telephone	E-mail
Quality Assurance QA	Robert Koch	+49 7463 99309 41	koch@smt-metalltechnik.de
Quality Management Representative	Priska Schilling	+49 7463 99309 14	<a href="mailto:priska.schilling@smt-metalltechnik.de">priska.schilling@smt-metalltechnik.de</a>
Quality Control QC	Juri Schwab	+49 7463 99309 33	schwab@smt-metalltechnik.de
Quality Control Assistant	Emanuela Xhufka	N/A	N/A
Quality Control Assistant	Mirella	N/A	N/A

## 6.3 Customer Service

Title	Name	Telephone	E-mail
Customer Service	Doris Zepf	+49 746399309 0	zepf@smt-metalltechnik.de
Customer Service	Anita Butz	+49 7463 99309 24	butz@smt-metalltechnik.de
Deputy CEO	Priska Schilling	+49 7463 99309 14	priska.schilling@smt-metalltechnik.de
President / CEO/ Owner	Erik Schilling	+49 7463 99309 20	schilling@smt-metalltechnik.de

## 6.4 Technical Sales

Title	Name	Telephone	E-mail
President / CEO/ Owner	Erik Schilling	+49 7463 99309 20	schilling@smt-metalltechnik.de
Design / Technical engineer	Alexander Stuwe	+49 7463 99309 21	stuwe@smt-metalltechnik.de

## 6.5 Round about Personal

Title	Name	Telephone	E-mail
Personal Manger	Alexander Stuwe	+49 7463 99309 21	stuwe@smt-metalltechnik.de



# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE



## 6.6 Other Contacts

Title	Name	Telephone	E-mail
IT Systems Engineer	Andreas Ovsjannikov	+49 7463 99309 22	ovsjannikov@smt-metalltechnik.de
Purchasing technical products	Alexander Stuwe	+49 7463 99309 21	stuwe@smt-metalltechnik.de
Invoices / payment accounts	Barbara Sorger-Schilling	+49 7463 99309 11	sorger-schilling@smt-metalltechnik.de

## 6.7 Emergency Accessibility

24h/7days availability in case of an emergency:	E-mail: <b>vorkommnis@smt-metalltechnik.de</b>
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## 7 Accounts Receivable Information

### 7.1 Bank Details

<b>Recipient</b>	SMT Schilling Metalltechnik GmbH
<b>Bank Name</b>	Raiffeisenbank Donau-Heuberg eG
<b>IBAN</b>	DE16643613590181492008
<b>BIC</b>	GENODES1RDH
<b>BLZ</b>	643 613 59
<b>Account No:</b>	181492008

<b>Recipient</b>	SMT Schilling Metalltechnik GmbH
<b>Bank Name</b>	Kreissparkasse Muehlheim
<b>IBAN</b>	DE45643500700008569653
<b>BIC</b>	SOLADES1TUT
<b>BLZ</b>	643 500 70
<b>Account No:</b>	8569653

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## 7.2 Payment terms

<b>Option 1</b>	Within 30 days without discount
<b>Option 2</b>	Within 14 days with 2% discount

**New Customers:** 10 Deliveries with payment in advance, than Option 1 or 2. If payment are not payed due to option 1, payment condition get back to payment in advance for next 10 deliveries

## 7.3 Availability of Invoices

<b>Are Invoices Available Online or via EDI</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Invoices are send with shipment and by E-mail
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## 8 Liability Insurance

THIS CERTIFICATION IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICY.	
Insurance Company	AXA Versicherung AG
Policyholder /Named Insured	SMT Schilling Metalltechnik GmbH Griesweg 33 78570 Muehlheim an der Donau
Business description:	Development, planning, design, production, trade and sale of surgical instruments and implants, as well as allied accessories, manufacturing of metal- parts.
Policy number:	70 23 71 65383
Policy period:	01/01/2017 to 01/01/2018
Scope of cover:	The scope of insurance cover is based upon the "Allgemeine Versicherungsbedingungen für die Haftpflichtversicherung– AHB" (German General Terms and Conditions of Liability Insurance) and the special terms of the policy.
Policy:	This policy provides cover for bodily injury and property damage worldwide. Cover also includes bodily injury and property damage caused by any products of the Insured after they have ceased to be in the custody or un- der the control of the Insured or by any operations after they have been performed and completed by the Insured (Product Liability/ Completed opera- tions).

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<p><b>Limits of indemnity:</b></p>	<p>The limit of indemnity for any one insured event is</p> <p><b>for the Public Liability and Product Liability risk</b></p> <p>5.000.000,00 EUR</p> <p>combined single limit for bodily injury and property damage according to Part III (Product Liability)</p> <p>The maximum annual aggregate for all insured events of any one insurance year shall amount to double these limits of indemnity.</p>
<p><b>Policy term</b></p>	<p>The insurance shall initially remain effective until 01/01/2017 and it shall be renewed automatically in each case by one year if it is not cancelled prior to next due date of expiry.</p>

## 9 Disaster recovery plan

A recovery plan is installed which covers failure of short time lost electricity, water, web and phone.

In case of a building burn down (Building 1,2 or 3) the production gets reduced due to the degree of disaster

## 10 Chemical Control

Procedures exist and are implemented detailing chemical control, not limited to but including the availability of MSDS sheets, disposal of waste, and required employee training

## 11 Animal Residues

We declare that all products supplied are totally free of any animal products (includes human and non-human sources). It is also our responsibility to ensure our whole manufacturing chain avoids the use of animal products (e.g. Polishes & Lubricants etc..) in the production of Products wherever possible.

## 12 Latex Residues

We declare that all products supplied are totally free of latex products. It is also our responsibility to ensure our whole manufacturing chain avoids the use of latex in the production of Products.

## 13 Safety

Safety is highest priority- proactive processes and audits demonstrate year-to-year improvement. Safety is important - there are actions based on employee suggestions being completed, there is a dedicated Health and Safety representative making continuous improvements, Health and Safety is reviewed periodically.

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## 14 Wastes

Entire organization is focused on waste elimination efforts. Employees have a strong understanding to minimize waste

## 15 Customer Service Level: Response time to enquiries

Our response time is:

- 1-2 days for standard products
- 2-5 days for special products where information from suppliers is needed

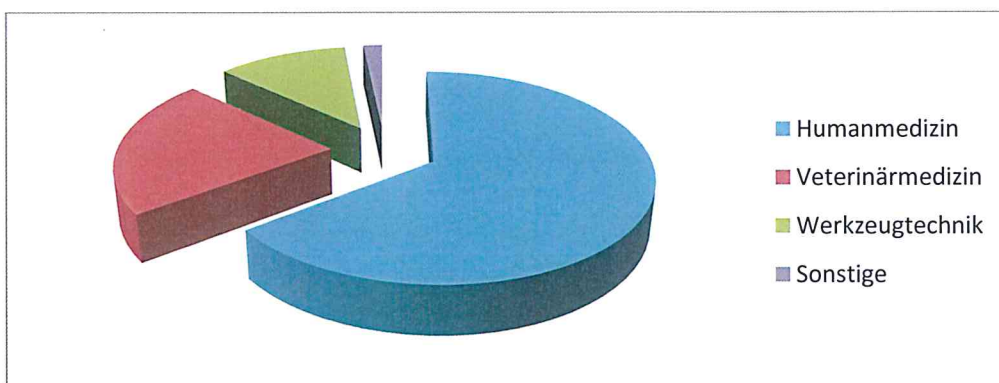
## 16 Social and Environmental Sustainability

SMT take care of:

- Respect for human rights
- No forced or compulsory labour
- No child labour (e.g. no workers under your Country's legal age , etc)
- Working conditions (e.g. mandatory days off, etc)
- Wages & benefits
- Non-discrimination (e.g. age, gender, religion, race etc.)
- Conflict minerals (Dodd-Frank Act, OECD due Dilligence Guidance)
- Energy (installed 190 KW photovoltaic system, LED lamps)
- Emmision (installed earthtemperature heating system, heat recovery)
- Water usage
- Waste management
- Restricted Substances and chemical handling

## 17 Sales

### 17.1 Percentages of Product groups

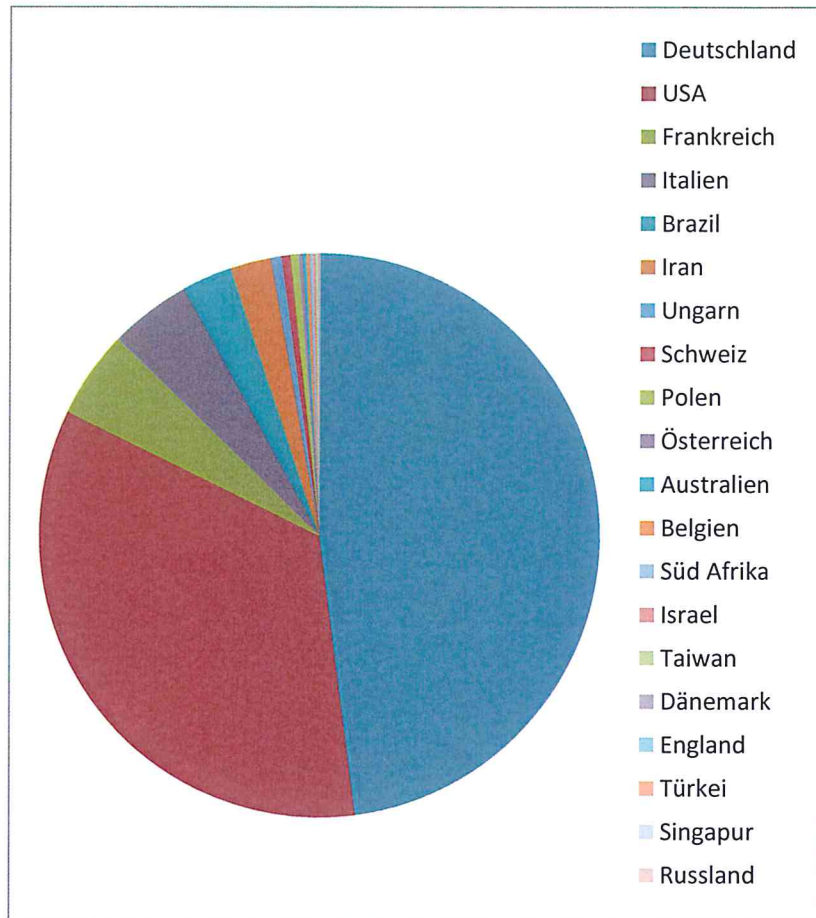


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## 17.2 Delivered Countries

Deutschland	47,55
USA	34,0
Frankreich	5,0
Italien	4,60
Brazil	2,90
Iran	2,30
Ungarn	0,60
Schweiz	0,52
Polen	0,45
Österreich	0,22
Australien	0,22
Belgien	0,19
Süd Afrika	0,16
Israel	0,13
Taiwan	0,13
Dänemark	0,08
England	0,03
Türkei	0,01
Singapur	0,01
Russland	0,009



# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE

## 18 Assurance of Supply Questions

1. Supplier founding year	SMT 1996 (Originally grouped in 1964)
2. Formerly known as (if applicable)	Schilling Mechanik GmbH
3. Legal form (corporation, LLC etc.)	GmbH
4. Is the company Public or Private?	Private
5. Is current business/annual report available?	Yes, www.bundesanzeiger.de
6. Can your company provide Instruction for Use as appropriate for all products supplied?	General Instruction for use and specific IFU
7. What is the Return policy?	See SMT Warranty Conditions
8. What is the Warranty policy?	2 years
9. Describe the environmental protection policy and its objectives?	Saving Energy, produce Energie (Photovoltaik), reduce waste as much as possible, Use of recyclable media
10. What is the human rights protection policy (child labor, fair trade etc)	Due to Youth employment law
11. Do you offer an electronic data interface that would allow us to provide forecasts, purchase orders and payments electronically?	No, currently not ( no existing interface to ERP)
12. Do you offer any web-based services (for example, to track order status, to access to certificate of analysis and other pertinent documentation)? If yes, please provide a brief description.	No, currently not ( no existing interface to ERP)
13. How many technical transfers from companies get performed in your site on an annual basis?	300-600 (technical drawings, technical questions)
14. What is your company's current on-time delivery track record. Please answer as % of orders delivered to customers on time.	+/- 5% on average. Stock items are possible to send sooner, special designed products, complicated and with involvement of more suppliers, can cause in a longer lead time as planned. Special note therefore in order confirmation
15. What is your company's current on-quantity track record?	Normally quantity as ordered, +10% if clarified with customer, minus percentage are checked with customer during production
16. Please provide the number of degreed engineers at the proposed site to review technical and analytical issues.	4
17. List any occupational injuries in the past 3 years requiring more than one lost work day or hospitalization:	0

# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE



18. What is the country or countries of origin of your raw materials?	Germany, France, Italy, USA, India
19. Is your company UDI compliant?	We deliver our products only to resellers which provide us their UDI code and we lasermark the products or print the labels with those
20. If not, what are your plans?	N/A
21. Will the supplier use GS1 bar code or data matrix?	Currently GS1 bar code and HRI, Data Matrix will follow as soon as verifier is installed
22. Is laser marking available for direct part marking?	Yes
23. Is chemical etching available for direct part marking?	Yes, due to customer wishes, but not validated
24. Will you offer volume discounts on pricing?	Yes, for special designed products, not for regular SMT products
25. Can you drop ship directly to our customers?	Yes, but charged
26. Is your company a C-PAT member? If so, please provide Status Verification Identifier (SVI).	No
27. Is your company a member of AEO or another WCO accredited security program administrated by a foreign customs authority? If so, please provide details and proof of status.	No
28. Please discuss the risk assessments that are conducted of your supply chain.	Risk Management Plan
29. Do you use seals that meet or exceed current PAS ISO 17712 standards for high security seals?	N/A
30. Do you have written procedures that describe how the seals are controlled during transit?	N/A
31. Are employees required to show an identification badge when entering your premises?	N/A Company size small and entering only through an controlled area
32. Are delivery personnel required to show photo identification upon arrival?	No
33. Do you verify application information such as employment history and references prior to employment?	No

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## 19 Regulatory Information

FDA Registered or Licenced	Yes
If yes, Registration / License Number	9680619
Date of Registration	1984
Has the FDA ever inspected this facility?	Yes, 2012/2015/2017
Are there any outstanding or unresolved issues with any government regulatory agency that may impact services provided ?	No
Is the facility ISO Certified?	Yes
Please list	DIN EN ISO 13485:2012 (Certificate see web-site ) <i>DIN EN ISO 9001:2008</i>
ISO Registration Number	Z/15/03583E, Report No: 661-15-422 <i>Z/15/03584D, Report No: 661-15-422</i>
Date of Registration:	June 11 <sup>th</sup> 2015; <i>June 11<sup>th</sup> 2015</i>
Expiration:	June 10 <sup>th</sup> 2018; <i>June 10<sup>th</sup> 2018</i>
Last ISO audit, (date)	April 2017
Other Audits	Different Customer Audits

### 19.1 Number of Associates

Administration	3
Quality	5
Manufacturing	25 (+12)
Research and Development	4
Engineering	3
Purchasing	5

### 19.2 Quality Rating System

Rating	Interpretation
Yes	affirmative to the question being asked
IP (In-Progress)	in progress, element of the QMS is currently being developed or changed
No	nothing implemented or not part of the QMS
N/A	not applicable (part of the QMS does not apply due to the service or product being provided)



# LIEFERANTENAUSKUNFT / SUPPLIER QUESTIONNAIRE

## 19.3 Management Responsibility

		Yes	IP	No	N/A
1	Has management defined and documented its policy for quality, including the company's objectives and commitment to quality?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Does management verify that the quality policy and objectives are available to all levels of the organization, understood, and implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Has the organization established, documented and defined the responsibility and authority of personnel who perform work affecting quality?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.4 Quality System

		Yes	IP	No	N/A
1	Has the organization established, documented and maintained a quality system, including a Quality manual?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are employees trained to comply with cGMP?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Does your organization carry out a comprehensive system of planned and documented internal quality audits?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Do internal quality audits verify compliance and effectiveness with quality objectives, systems and continuous quality improvement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Is there a training system in place that identifies training needs for all levels of employees whose work impacts the quality of the product or service?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Is training documented and training records maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	If servicing is a requirement, are there procedures to cover its performance and verification of effectiveness and reporting?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8	Are specifications available during service and repair activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

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## 19.5 Design Control

		Yes	IP	No	N/A
1	Does the organization establish and maintain plans that describe or reference the design and development activities and define responsibilities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are design changes documented and approved by authorized personnel before implementation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are design history files (DHF) updated and maintained to reference the records necessary to demonstrate that the designs were developed in accordance with the approved design plan?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.6 Document Control

		Yes	IP	No	N/A
1	Does the organization have a system in place for the control of documents that affect quality systems, regulatory systems or product/process related systems?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Does the organization have a system in place for signature authority of controlled documents?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Does the organization ensure that employees have access to the most recent version of a procedure or standard?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are document changes recorded in the document or on an appropriate attachment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Are documents available at the point of use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Are invalid or obsolete documents withdrawn or otherwise prevented from accidental use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Does the organization have a document retention procedure / policy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Does the organization have a procedure for the control of national/international standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

# LIEFERANTENAUSKUNFT / SUPPLIER QUESTIONNAIRE

## 19.7 Supplier Control and Purchasing

		Yes	IP	No	N/A
9	Does the organization have procedures that govern the selection, approval, and ongoing evaluation process to control the purchases of equipment, materials, and services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Does the organization utilize an approved supplier list?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Are there procedures to ensure that purchased or otherwise received product, equipment, materials, and services meets specified requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Are subcontractors regularly monitored for adherence to predetermined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Are there established procedures for review of contracts, services agreements, and quality agreements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.8 Material Identification and Traceability

		Yes	IP	No	N/A
1	Does the organization have procedures defining product and equipment identification requirements for all materials, products, or equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are individual products, batches or lots controlled with a unique identification system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are raw materials used in manufacturing traceable throughout the entire process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are materials clearly segregated and labeled based on their stock status (i.e., quarantine, non-conforming, released)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Are equipment used in manufacturing traceable through the entire process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE

## 19.9 Process Control/Change Control

		Yes	IP	No	N/A
1	Are there documented procedures that define how the organization controls the manufacturing, service, production and/or any other GMP related process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Is there a formal batch record of production steps, raw materials used, batches, and quantities used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Is there a change control process in place that captures any addition, deletion or modification made to equipment, processes or systems that are implemented in conformance to regulatory requirements or have GXP impact?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Is there a process in place that identifies the risk or impact to proposed changes in production or manufacturing of product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Is there a process in place that notifies clients of changes in manufacturing processes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Are controlled environments and clean rooms monitored for environmental excursions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7	As a result of an environmental excursion, are product impact assessments performed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8	Does the organization have documented procedures for cleaning and preventive maintenance of equipment and work areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Are cleaning or sterilization processes validated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Are computer systems that control the process or collect data validated?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Are line clearances performed between different manufacturing operations before they begin?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Are there established procedures for conducting periodic inspections of raw material and product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Are inspection criteria's defined in your SOPs/Specs/Drawings etc.?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Are there procedures that ensure that all inspection and test equipment are suitable for its intended purpose and calibrated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Does the organization have a calibration program to identify the equipment, calibration dates, individual performing each calibration, and the next calibration date?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): Some validations still in process					

# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE



## 19.10 Nonconforming Products

		Yes	IP	No	N/A
1	Are there documented procedures for control of nonconforming materials, products, services, and equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are reworked products re-inspected in accordance with company procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are non-conforming materials / products clearly segregated from materials / products that have passed final inspection?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.11 Corrective Action/Preventative Action

		Yes	IP	No	N/A
1	Does the organization have and implement a formal CAPA procedure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are root cause analysis or other methodologies utilized to uncover trends and provide support for implemented corrective actions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are CAPAs and CAPA trends discussed during Management Review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Does the organization have a formal complaint procedure that documents all complaints and their corresponding investigations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Are corrective action requests issued to a supplier when a quality problem exists?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.12 Packaging, Handling, Storage, and Delivery

		Yes	IP	No	N/A
1	Are there procedures in place for handling, storing, packaging and delivery of product or equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Does the organization provide secure storage areas that prevent damage and deterioration?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Do packaging and shipping records reflect the individuals performing and inspecting the shipping operations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Have shipping conditions (packaging / methods) been validated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): To 4: Not validated but by a customer feedback due to a response letter checked and released					

# LIEFERANTENAUSKUNFT/ SUPPLIER QUESTIONNAIRE

## 19.13 Records and Complaints Handling

		Yes	IP	No	N/A
1	Do procedures exist for identification, collection indexing, access, filing, storage, maintenance and disposition of quality records (i.e. does a quality system exist)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are all records controlled under a change control system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Do procedures exist for the receipt, review and evaluation of complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are all records protected from damage and deterioration?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Do you maintain Device History Records (DHR)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Do you maintain Device Master Records (DMR)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 19.14 Statistical Techniques

		Yes	IP	No	N/A
7	Has the need for statistical techniques identified for controlling and verifying processes been identified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Are sampling plans based on recognized standards, if not is there documented statistical rationale?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Are reduced/heightened sampling documented through procedures or statistical rationale?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments (please explain any "In-progress or No" responses): N/A					

## 20 Confidential Agreement

<b>Dokumentenpfad, Nummer und Name</b>	erstellt/geändert	2017-11-27	freigegeben/geprüft	2018-01-02	Seite /	Seiten
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