Dornier MedTech is a manufacturer of medical devices. To fulfill the requirements according to ISO 13485 in evaluation of suppliers, we created this questionnaire. By this questionnaire we want to keep the number of audits as low as possible for mutual benefit.

However we depend on your support. Please fill in the questionnaire and indicate questions which are not applicable with NA.

A) Company Information	
Company Name	
Street and house number	
Zip and City	
SRN (Single Registration number) from EUDAMED, if applicable	
Name, Quality Management Representative Phone Fax Email	
Founding year	
Average Number of Employees at this site during the last 3 years:	Year # Year # Year #
Thereof how many Employees work actually in the production and the quality assurance	Production # Quality Assurance # Please supply a current copy of Organizational chart
Average Sales Volume for last 3 year	Year # Year # Year #

B) Scope Manufacturing and Services
☐ Turning / Milling part ☐ Welding / molding / bonding ☐ Electrical Assembly ☐ Mechanical Assembly ☐ Painting ☐ Boards Assembly ☐ Contract Development Electrical ☐ Contract Development Mechanical ☐ Contract Development Optics ☐ Service Provider of : ☐ etc. – please specify :

C) QMS Part 1		
Is your Quality Management System certified by an external party?	☐ Yes ☐ No	If "**Yes**", please indicate the relevant certificate and skip Part D): ☐ (EN) ISO 13485:2012 ☐ (EN) ISO 13485:2016 ☐ (EN) ISO 9001:2008 ☐ (EN) ISO 9001:2015 ☐ other standard (please specify) : Please provide a copy of Certificate. If "**No**", please answer additionally "D) QMS Part 2"
If Dornier MedTech wants to conduct an audit, How much lead time do you need for planning?		
Are any process steps / services subcontracted? If Yes, please list the provided in detail	☐ Yes ☐ No	
Are there any Quality Agreements with the subcontractors?	☐ Yes ☐ No ☐ Not applicable	

How long is the documentation of production, trading and quality system stored?	
How is the documentation done, paper based or electronical?	☐ paper based ☐ electronical Remarks:
Are the products checked and released prior to sale?	☐ Yes ☐ No ☐ Not applicable
Are the delivered products labeled with name, material number, lot and manufacturing date?	☐ Yes ☐ No ☐ Not applicable Remarks:
Is the traceability given a) from the product to the source of material or manufacturer b) from the product to the customers?	a) ☐ Yes ☐ No ☐ Not applicable b) ☐ Yes ☐ No ☐ Not applicable
Are the customers informed about changes to the product in advance?	☐ Yes ☐ No
Are the customers informed about deficiencies which are detected after the sale?	☐ Yes ☐ No ☐ Not applicable
Does the QM-department investigate and resolve quality complaints	☐ Yes ☐ No
Is there a process for corrective and preventive actions (CAPA) or a continuous improvement process (CIP) installed?	☐ Yes ☐ No
Are periodic self-inspections or management reviews be performed?	☐ Yes ☐ No

D) QMS Part 2 (edit only if you answered *C) QMS Part 1* Question 1 with "No")

Does your company plan to be certified according to one of the mentioned standards? Please indicate the standard.	☐ Yes ☐ No ☐ (EN) ISO 13485:2016 ☐ (EN) ISO 9001:2015 ☐ other standard (please specify) When do you plan the certification? Remarks:

Is your Quality Management System documented by a Quality Manual and/or written procedures?	☐ Yes ☐ No Remarks: Please provide a list of procedures:
Has your Quality Management System already been audited by other companies?	☐ Yes ☐ No
Are staff trainings performed? Is there any system for staff training?	☐ Yes ☐ No ☐ Yes ☐ No
Is there any access control to critical premises, documents and data?	☐ Yes ☐ No
Are the processes executed documented?	☐ Yes ☐ No

E) Environmental Compliance

Has your company/site implemented a system for monitoring regulated substances in your products?	☐ Yes ☐ No ☐ Not applicable
Does your company comply with the DIN EN IEC 63000 or DIN EN 50581?	☐ Yes ☐ No ☐ Not applicable
Does your company perform risk assessments or chemical tests for bought-in semi-finished products or materials?	☐ Yes ☐ No ☐ Not applicable
Does your company have a Material-Compliance or Product Compliance Officer position?	☐ Yes ☐ No ☐ Not applicable

Are you complying with the Directives/Standards/Acts below

Directives/Standards/Acts	Awareness		Applicable to your products/Processes		Do you comply with these?		Can you provide a Certificate of conformity?	
	Yes	No	Yes	No	Yes	No	Yes	No
ISO 14001	☐	☐	☐	☐	☐	☐	☐	☐
RoHS 2 2011/65/EU	☐	☐	☐	☐	☐	☐	☐	☐
WEEE 2012/19/EU	☐	☐	☐	☐	☐	☐	☐	☐
REACH EC 1907/2006	☐	☐	☐	☐	☐	☐	☐	☐
Packaging and Packaging waste Directive 94/62/EC	☐	☐	☐	☐	☐	☐	☐	☐

F) CE marking	
Are your products CE marked?	☐ Yes ☐ No ☐ Not applicable
If yes, under which directive	
If yes, provide CE marking certificate	

G) References – *please fill if providing service*		
Does your company work for other medical device or pharma customers?	☐ Yes ☐ No	
Does your company work for other regulated industries like aerospace, defence industry, nuclear power?	☐ Yes ☐ No	
Please provide 3 customer references		
Company Name	Location	Sector

H) Name, Date, Signature	
Name	
Position	
Date	
Signature	

Thank you for your support!