This questionnaire serves to obtain information from you and your product/development with the goal to prepare in an efficient way further discussions and customized offers.

Please return the completed questionnaire plus attachments to the following e-mail address:
medtech@item.fraunhofer.de

1. General information

Company name:	
Address:	
Filled by:	
Date:	

Do you have an organizational unit that addresses quality management?	
☐ Yes, but it is not certified. ☐ No, there is no experience with quality management. ☐ Yes, it is certified according to EN ISO 13485. ☐ No, but there is experience with quality management. ☐ Yes, it is certified according to EN ISO 9001.	
Do you have personnel dealing with the regulatory affairs of medical devices?	
☐ No	☐ Yes, contact person (Name, E-Mail):

2. Product information

Name of the product(s):
How is the product used?
☐ The intended purpose/use (medical purpose, medical application, use) is not determined yet. Please describe the product in the field below. ☐ The intended purpose/use (medical purpose, medical application, use) is (partially) determined. Please add the intended purpose/use.
Description (please be as detailed as possible):

Is the risk class (acc. to MDR 2017/745) known?		
☐ No, it is not known.	☐ Yes, risk class:	Rule:
Does the product contain pharmaceuticals?		
☐ No, it doesn't contain pharmaceuticals. ☐ Yes, it contains pharmaceuticals. Please specify the pharmaceuticals:		
Does the product contain software?		
☐ No, it doesn't contain software. ☐ Yes, it contains software. Please specify the software:		
List of accessories, if available:		
Is the medical device already placed on a European, US or other market? If so, on which market?		
☐ No, it has not been launched yet. ☐ Yes, it has been launched on the market. Please specify the market(s):		
Are there previous generations of this medical device?		
☐ No, there is no previous device.	☐ Yes, the product is a further development of:	
Are there similar products (from other manufacturers) on the market?		
☐ No idea. ☐ No, there are none known.	☐ Yes, these are:	

3. Existing documentation

Device description and specification (e.g. intended purpose, variants, accessories, materials, IFU, surgical technique):	☐ Yes	☐ Partially	☐ No
Design and Manufacturing Information:	☐ Yes	☐ Partially	☐ No
General Safety & Performance Requirements (GSPR):	☐ Yes	☐ Partially	☐ No
Risk Analysis and Risk Management:	☐ Yes	☐ Partially	☐ No
Product Verification and Validation (e.g. biocompatibility, packaging, stability, shelf-Life, usability):	☐ Yes	☐ Partially	☐ No
Clinical Evaluation:	☐ Yes	☐ Partially	☐ No
Design History (Change Documentation):	☐ Yes	☐ Partially	☐ No
Declaration of Conformity	☐ Yes	---	☐ No
Other, please specify:			

4. What are your requirements, wishes and expectations?

Desired scope of services? How can we help? What are your next milestones?
☐ Support with the compilation of technical documentation for product placing on the market (CE)
☐ Support with the compilation of technical documentation for product placing on the market (FDA)
☐ Support with development testing / development projects
☐ Support with biological assessment (ISO 10993-1).
☐ Support with risk management (ISO 14971).
☐ Support with product verification and validation.
☐ Support with QMS-Establishment (ISO 13485).
☐ Other, please specify:

Time limits (e.g. planned market entry)?

Please attach the following documents, if available
☐ Product Information
☐ Instructions for Use (IFU)

Appointments for an initial meeting (please select dates and times)	
Option 1 (Date, Time):	
Option 2 (Date, Time):	
Option 3 (Date, Time):	

How did you hear about us?