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REQUEST SERVICE

This form is filled out in order to collect and define the initial data and inputs needed to focus the required service. Please select from the following list the type of activity and you will be then redirected to the applicable table:

	Service	Selection	Reference
Product Design and Development			
Single service	FEM Simulation		Table 1
	Rapid Prototyping		Table 2
	Reverse Engineering		Table 3
	3D Modelling		Table 4
	Complete Design / NPD		Table 5
Validation, Quality and Regulatory			
	Regulatory Activities		Table 6
	Quality System		Table 7
	Validation IQ / OQ / PQ		Table 8
Testing activities			
	Chemical/Physical Tests		Table 9
	Mechanical Tests		Table 10
	Biocompatibility Tests		Table 11

Table 1 - FEM Simulation

Device Description	
Material	
Device image	
Device classification	
Reason for which the test is required	<input type="checkbox"/> Validation and Verification <input type="checkbox"/> Defects of component / product <input type="checkbox"/> Quality check <input type="checkbox"/> Other
Stress (mechanical, heat, electromagnetic, vibration, etc ..)	
Load conditions you would like to simulate (static, dynamic)	
Reference test and / or reference standards (if known)	
Attach 3D model of the device	

Table 2- Rapid Prototyping

Type of Device	
Application Fields	
Required functionality	
Feature/ Material	
Resolution needed	
Component size	
Timeline	
Other	

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Table 3 - Reverse Engineering	
Type of Device	
Application Fields	
Required functionality	
Component size (Photos attached)	
Resolution	
Output file requested	
Timeline	
Other	



Table 4 - 3D Modeling

Type of Device	
Application Fields	
Required functionality	
Component size	
Attach 2D sketch of component (if available)	
Output file required / CAD System	
Timeline	
Other	

Table 5 - Design - New Product Development

Type of Device	
Application Fields	
Required functionality	
Device classification	
Predicate Device (if available)	
Further information	

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Table 6 - Regulatory Activities	
Type of Device	
Application Fields	
Classification according to MDD 93/42	
Target market (EU, US)	
Documentation required (if already defined) Ex. Technical File / DHF / Risk File	
Predicate Reference Device	
Timeline	

Table 7 - Quality System

Type Devices / Products	
Application Fields	
Reference market (EU, US)	
Desired Certification	
Production processes	
Timeline	

Table 8 - Validation IQ / OQ / PQ

Type of Process	
Output Process	
Classification device subjected to the process	
Specific regulations for the process	
List of equipment and machines used in the process	
Specific tests and acceptance criteria (if available)	
Attach machines manuals	
Equipment already installed and tested?	
Are purchase specifications present?	
Are URS (User Requirement Specification) been defined?	

Table 9 - Test Chemical Physical

Select from the proposed tests list	Moisture content (Karl-Fisher method)	<input type="checkbox"/>
	Density	<input type="checkbox"/>
	Analysis of the fibers	<input type="checkbox"/>
	Permeability to water vapor	<input type="checkbox"/>
	Global migration	<input type="checkbox"/>
	Thermal diffusivity	<input type="checkbox"/>
	Differential scanning calorimetry (DSC)	<input type="checkbox"/>
	Determination of the softening temperature (VICAT)	<input type="checkbox"/>
	Thermogravimetric analysis (TGA)	<input type="checkbox"/>
	Coefficient of linear thermal expansion	<input type="checkbox"/>
	Heat resistance	<input type="checkbox"/>
	Specific migration	<input type="checkbox"/>
	Elemental analysis (determination of % C, % H, % N, % S)	<input type="checkbox"/>
	Tensions (using solvents)	<input type="checkbox"/>
	Oxygen permeability	<input type="checkbox"/>
	Determination of heavy metals	<input type="checkbox"/>
	Determination of solid and liquid pH	<input type="checkbox"/>
	Dimensional stability	<input type="checkbox"/>
	Deterioration in ozone	<input type="checkbox"/>
	Qualitative detection of plasticizers	<input type="checkbox"/>
Accelerated aging Xenotest (UV rays)	<input type="checkbox"/>	
Defect analysis	<input type="checkbox"/>	
If you know the test you want to run but it is not listed		
Reason for which the test is required	<input type="checkbox"/> Validation and Verification <input type="checkbox"/> Defects of component / product <input type="checkbox"/> Quality check <input type="checkbox"/> Other	
Add / specify details if relevant		

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Test material (commercial code, formula if known)	
Specific regulatory requirements	
State of delivered samples	
Ideal times for receipt of test results	

Table 10 - Mechanical Test

Specify the type of test required: static test, dynamic, fatigue, wear, functional etc ..	
Reason for which the test is required	<input type="checkbox"/> Validation and Verification <input type="checkbox"/> Defects of component / product <input type="checkbox"/> Quality check <input type="checkbox"/> Other
Add / specify details if relevant	
Test material (commercial code, formula if known)	
Classification of the tested device (MDD or other applicable regulations)	
Specific regulatory requirements for testing	
Sample delivery	
State of delivery samples	
Ideal times for receipt of test results	
Attach the component design to be tested	
Attach reference Test Report (if available)	
Support equipment (specify if available or has to be made)	

Table 11 - Test Biocompatibility

Device Description	
Material	
Device image	
Classification according to MDD 93/42	
Contact Nature	<input type="checkbox"/> surface device <input type="checkbox"/> device in communication with the 'external <input type="checkbox"/> implantable device
Contact life	<input type="checkbox"/> ≤ 24 hours - limited (1) <input type="checkbox"/> 24 hours <to <30 days - extended (1) <input type="checkbox"/> <30 days - Permanent (2) (1) Consider also more contacts each time with new devices (Eg. Catheter) (2) Consider the sum of repeated contacts with the same device
Device Composition	<input type="checkbox"/> only plastic <input type="checkbox"/> only metal <input type="checkbox"/> only ceramics. <input type="checkbox"/> plastic and metal / ceramic / glass For device with more 30 days contact specify if it is: <input type="checkbox"/> resorbable polymer <input type="checkbox"/> inorganic material resorbable <input type="checkbox"/> metal with absorbable coating
Contact with blood circulation	<input type="checkbox"/> nobody <input type="checkbox"/> indirect <input type="checkbox"/> direct
Product status	<input type="checkbox"/> Sterile <input type="checkbox"/> non Sterile
Shipped to TS	
Customer supplied	<input type="checkbox"/> Sterile <input type="checkbox"/> non Sterile <input type="checkbox"/> ever used <input type="checkbox"/> used once <input type="checkbox"/> used repeatedly
Use	<input type="checkbox"/> non Sterile <input type="checkbox"/> Sterile
Type of sterilization used	<input type="checkbox"/> steam sterilization <input type="checkbox"/> sterilization in ethylene oxide <input type="checkbox"/> sterilization by irradiation <input type="checkbox"/> Sterilization NTP (Non Thermal Plasma) <input type="checkbox"/> others _____
Contact surface [cm2]	