

Introduction

This leaflet is prepared to guide prospective clients through the process of completing the SI.FR.07.01 - Request for Quote (RFQ) Form, which is available at www.notice.si.

1. Legal Manufacturer Information					
Legal Entity Name	<i>Provide the full name of the company, exactly as it appears on the company business license.</i>				
Addresses	Registered HQ:	<i>Write the address of the company headquarters, exactly as it appears on the company business license</i>			
	Registered Production:	<i>Write the address(es) where the production of the device(s) takes place.</i>			
	Warehouse:	<i>Write the address(es) where warehouses are located.</i>			
	Packaging:	<i>List the address(es) where the packaging process is carried out.</i>			
	Sterilization:	<i>List the address(es) where the sterilization process is carried out.</i>			
	R&D:	<i>List the address(es) where the R&D process is carried out.</i>			
	Other:	<i>Provide any additional address(es) not mentioned above, along with the specific process(es) conducted at each location.</i>			
<p>1- <i>If there are multiple addresses associated with any of the processes mentioned above, please list all of them in the corresponding cell.</i></p> <p>2- <i>If any of the processes mentioned above are subcontracted, please include the subcontractor's name and address in the corresponding cell.</i></p> <p>3- <i>If any of the processes mentioned above do not apply to your device or QMS, please enter "N/A" in the corresponding cell.</i></p>					
Phone	<i>Provide the company's phone number.</i>		E-mail	<i>Provide the company's e-mail address.</i>	
Web	<i>Provide the company's webpage.</i>		VAT Number	<i>Provide the company's tax number.</i>	
No. of Full-time Effective Employees	<i>Write the number of full-time employees who work directly for the device or maintaining the QMS activities (e.g.: personnel involved in design, manufacturing, sales, warehousing of device or personnel in quality department, top management, etc.)</i>		No. of Part-time Effective Employees	<i>Write the number of part-time employees who work directly for the device or maintaining the QMS activities (e.g.: personnel involved in design, manufacturing, sales, warehousing of device or personnel in quality department, top management, etc.), if any. In case there is no part-time employee, write NA or 0.</i>	
			No. of Shifts*	<i>Write the number of operational shifts in the company.</i>	
*In case the operations in multiple shifts are different, list of processes in each shift:					
<i>In case of multiple operational shifts, provide the list of all conducted processes in each shift separately (i.e. For day shift, evening shift and night shift), In case of one single shift, write NA.</i>					

1. Legal Manufacturer Information			
Registered Competent Authority	Provide the full name of competent authority ¹ of the company.	Single Registration No.	Provide the single registration number (SRN) for the company.
Authorized Signatory	Provide the name of the individual holding the authority to sign legal contracts in the name of the company.	e-mail	Provide the e-mail address of the corresponding person in here.
Management Rep.	Provide the name of management representative in here.	e-mail	Provide the e-mail address of the corresponding person in here.
Person Responsible for Regulatory Compliance (PRRC)	Provide the name of person in charge of regulatory compliance ² .	e-mail	Provide the e-mail address of the corresponding person in here.
Affiliated organizations (if any)	If company is a part of a larger entity, or has subsidiaries and branches, provide the name of those organizations.		

2. Authorized Representative Information (if applicable)					
<i>This part is filled in by a company that is located outside of member states³.</i>					
Legal Entity Name	Provide the name of the authorized representative ⁴ in here.				
Registered Address	Provide the address of the authorized representative in here.				
Contact Person	Provide the name of the contact person in the authorized representative.	Phone	Provide the phone number of the contact person of authorized representative.	e-mail	Provide the e-mail address of the contact person of the authorized representative.
Competent Authority	Provide the full name of competent authority ⁵ of the country of the authorized representative.	Single Registration Number (SRN)		Provide the single registration number (SRN) for the authorized representative.	

3. Requested Services
3.1. Certification under EN ISO 13485
<input type="checkbox"/> EN ISO 13485:2016 QMS <input type="checkbox"/> Certification <input type="checkbox"/> Transfer <input type="checkbox"/> Scope Extension <input type="checkbox"/> Recertification* <input type="checkbox"/> Others:
<p>* For Recertification, significant changes to the QMS or organization, shall be communicated to NOTICE via SI.FR.08.11 Planned Change Notification Form.</p> <p><i>If you are applying for ISO 13485 certification service, check this box and mark the related service as explained below:</i></p> <p><i>In case you don't have any valid ISO 13485 QMS certificate, mark "Certification".</i></p> <p><i>If you have a valid ISO 13485 certificate from another organization and you wish to change your certification body to NOTICE d.o.o., mark "Transfer".</i></p>

¹ For the list of competent authorities, refer to https://health.ec.europa.eu/document/download/c28e965a-3b7c-4a5b-a6ee-d1724d06f20d_en?filename=md_contact_points_of_national_authorities.pdf

² Person designated based on the requirements of EU 2017/745 MDR Article 15.

³ For the list of member states, refer to https://european-union.europa.eu/easy-read_en

⁴ Entity designated based on the requirements of EU 2017/745 MDR Article 11.

⁵ For the list of competent authorities, refer to https://health.ec.europa.eu/document/download/c28e965a-3b7c-4a5b-a6ee-d1724d06f20d_en?filename=md_contact_points_of_national_authorities.pdf

If you have a valid ISO 13485 certificate from NOTICE d.o.o. and you want to extend the certification scope (addition of new devices or services), mark "Scope Extension".

If you have a valid ISO 13485 certificate by NOTICE d.o.o. that is about to expire, mark "Recertification".

If there have been any changes to your QMS or organization since the last surveillance audit, please fill in the SI.FR.08.11 Planned Change Notification Form published on our website (<https://notice.si/services/documents/documents.htm>) and submit it to NOTICE along with this RFQ.

For any other cases, (such as address change, scope reduction...), mark "Others" and provide details on your request.

Requested ISO 13485 Scope	<p>Provide the requested QMS scope. The QMS scope is a general summary of your QMS activities for your device or service. It is decided in your quality manual.</p> <p>You need to use the Technical Areas described in Annex A of IAF MD9 to define the scope. For instance,</p> <ul style="list-style-type: none"> - if you are a designer, manufacturer and seller of "Device X", your scope would be: "Design, manufacture and sales of Device X." - if you are only the provider of sterilization service to medical devices, your scope would be "sterilization services for medical devices."
ISO 13485 excluded or not applicable clauses	<p>Write the articles of EN ISO 13485 which are not applicable to your QMS.</p> <p>You are allowed to exclude only requirements that appear in clauses 6, 7, or 8 of the ISO 13485 Standard For instance,</p> <ul style="list-style-type: none"> - if you do not provide any servicing of the medical devices, exclude 7.5.4, - if you are a designer, manufacturer and seller of non-active, non-sterile, non-implantable devices, the possible excluded clauses for your QMS would be: "7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2"

3.2. Certification under MDR

Device list

List the devices that you are requesting MDR certification for.

EU 2017/745 Medical Device Regulations

Annex IX Conformity Assessment Based on a Quality Management System & Assessment of Technical Documentation

Annex XI Part A, Production Quality Assurance**

Certification Transfer Scope Extension Recertification Others:

If you are requesting EU 2017/745 MDR conformity assessment service, check this box, and mark the appropriate conformity assessment route according to the following table.

Devices	Conformity Assessment Procedures
Class III implantable	Annex IX (Chapter I & III + Chapter II section 4) OR Annex XI (Part A), coupled with an EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X already issued by another Notified Body
Class III- non implantable (including devices with medicinal substances & class III Rule 21)	Annex IX (Chapter I & III + Chapter II section 4) OR Annex XI (Part A), coupled with an EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X already issued by another Notified Body
Class IIb (rule 12)	Annex IX (Chapter I & III + Chapter II section 4) OR Annex XI (Part A), coupled with an EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X already issued by another Notified Body
Class IIb (Implantable, except for WET)	Annex IX (Chapter I & III + Chapter II section 4) OR Annex XI (Part A), coupled with an EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X already issued by another Notified Body
Class IIb (Non implantable, non-rule 12, non-WET & Implantable WET)	Annex IX (Chapter I & III + Chapter II section 4) OR

	Annex XI (Part A), coupled with an EU type-examination certificates referred to in MDR 2017/745 Section 4 of Annex X already issued by another Notified Body
Class IIa	Annex IX (Chapter I & III + Chapter II section 4) OR Annex XI (Part A, section 10)
Class I (s/m/r)	Annex IX (Chapter I & III) OR Annex XI (Part A, section 10)

Choose the requested service and mark the related box as explained below:

If you don't have a valid MDR certificate for the device in question, mark "Certification".

If you have a valid MDR certificate from another organization and wish to change your notified body to NOTICE d.o.o., mark "Transfer".

If you have a valid MDR certificate from NOTICE d.o.o. and you want to extend the certification scope (addition of new devices), mark "Scope Extension".

If you have a valid MDR certificate from NOTICE d.o.o. that is about to expire, mark "Recertification".

For any other cases (address addition, scope reduction...), mark "Others" and provide details on your request.

**** In case of requesting Production quality assurance certificate according to Annex XI, Part A, for class IIb and III devices, Annex X type examination certificate information**

Issuing NB:		Certificate No.:	
Issue Date:		Valid until:	
Certificate Scope:			

In case of requesting Annex XI-Part A, you need to have a valid EU 2017/745 MDR Annex X Type examination certificate. Provide the certificate details in the boxes above and attach a copy of the certificate to this RFQ.

*The certificate shall be provided along with the RFQ.

4. Outsourced Processes, Suppliers & Subcontractors

Outsourced Processes	<input type="checkbox"/> Design & Development	<input type="checkbox"/> Production
	<input type="checkbox"/> Sterilization	<input type="checkbox"/> Storage
	<input type="checkbox"/> Other (Specify):	

Mark any outsourced processes.

The **outsourced process** are the ones performed outside the organization. This **does not** relate to purchased goods, materials, or components, but to the provision of core processes needed for the realization of the product supplied by suppliers or contractors: design and development, production, assembly, sterilization, cleaning, accreditation, storage, and transportation.

If your outsourced process is not listed above, mark "Other:" and provide the name of outsourced process in corresponding cell.

Subcontractor/Critical Supplier Information

#	Critical Supplier Name& Address	Related Device	Rendered Service	Service Description	No. of Employees	QMS/MDR Certificate*
1	Name:		<input type="checkbox"/> R&D <input type="checkbox"/> Production <input type="checkbox"/> Partial Production <input type="checkbox"/> Sterilization <input type="checkbox"/> Component <input type="checkbox"/> Raw material <input type="checkbox"/> Other			
	Add:					
2	Name:		<input type="checkbox"/> R&D <input type="checkbox"/> Production <input type="checkbox"/> Partial Production			

	Add:		<input type="checkbox"/> Sterilization <input type="checkbox"/> Component <input type="checkbox"/> Raw material <input type="checkbox"/> Other		
3	Name:		<input type="checkbox"/> R&D <input type="checkbox"/> Production <input type="checkbox"/> Partial Production <input type="checkbox"/> Sterilization <input type="checkbox"/> Component <input type="checkbox"/> Raw material <input type="checkbox"/> Other		
	Add:				
	<p><i>Provide name and address of your critical supplier/subcontractor in corresponding cells.</i></p>	<p><i>List the device(s) that the supplied material or subcontracted service is used for.</i></p>	<p><i>In "Rendered Service" column, mark the subcontracted process or supplier type. If not given in the list, mark "Other" and provide details.</i></p> <p><i>In "Service Description", provide details regarding to supplied or subcontracted service, as explained below:</i></p> <ul style="list-style-type: none"> - <i>In case you mark R&D, list the outsourced R&D stages(s) as description.</i> - <i>Mark "Production": if you subcontract the whole manufacturing process to another organization. In "Service Description", list the manufacturing processes which are outsourced.</i> - <i>Mark "Partial Production": if you subcontract a part of your production process. In "Service Description", list the manufacturing processes which are outsourced.</i> - <i>Mark "Sterilization" if you subcontract sterilization , In "Service Description", provide the sterilization method.</i> - <i>Mark "Component" if you purchase components of your device from another company. In "Service Description", provide the name of the component.</i> - <i>Mark "Raw Material" if if you purchase raw materials from another company. In "Service Description", provide the name of the raw material.</i> - <i>Mark "Others:" if the service is not listed there. In "Service Description", provide the details of the service.</i> <p><i>In "Number of Employees" cell, write the number of employees of subcontractor or supplier.</i></p> <p><i>In "QMS/MDR Certificate" cell, write the certificates the suppliers/ subcontractors have and attach a copy of the certificates to the RFQ.</i></p>		

*** Certificates should be attached to this form or be available upon request.**

5. Documentation & Certificates

QMS documentation completed?

Yes
 No

QMS Effective Date: _____ Estimated Completion Date: _____

Language of QMS documentation: _____

If your QMS documentation is completed, mark "Yes" and write the date that you started implementing your QMS in "QMS Effective Date:" cell and the language in corresponding cell.

In case the QMS documentation is not completed yet, mark "No" and provide information on estimated completion date of QMS and the language of documents in corresponding cells.

Technical documentation completed?				
<input type="checkbox"/> Yes		<input type="checkbox"/> No		
Technical Documentation Issue Date:		Estimated Completion Date:		
<i>If your technical documentation is completed, mark "Yes" and write the issue date of technical documentation in corresponding cell.</i>				
<i>Otherwise, Mark "No" and write the estimated completion date in corresponding cell.</i>				
Current Certificates Status				
<i>Provide information on certificates of device and QMS as described below.</i>				
<input type="checkbox"/> The devices are already certified to MDR.		CAB:		Expiration Date:
Certificate Scope:				
<i>Mark this box if you already have a valid MDR certificate from another notified body and have marked "Transfer" as the requested service in part 3,</i>				
<ul style="list-style-type: none"> - <i>In the "CAB" cell, enter the name of the notified body that issued your certificate.</i> - <i>In the "Expiration Date" cell, specify the date on which the certificate expires.</i> - <i>In the "Certificate Scope" cell, list the devices covered under the certificate.</i> 				
<input type="checkbox"/> The devices are already certified to MDD.		CAB:		Expiration Date:
Certificate Scope:				
<i>Mark this box if you already have a valid MDD certificate from another notified body,</i>				
<ul style="list-style-type: none"> - <i>In the "CAB" cell, enter the name of the notified body that issued your certificate.</i> - <i>In the "Expiration Date" cell, specify the date on which the certificate expires.</i> - <i>In the "Certificate Scope" cell, list the devices covered under the certificate.</i> 				
<input type="checkbox"/> The manufacturer is already certified to ISO 13485:2016.		CAB:		Expiration Date:
Certification scope:				
<i>Mark this box if you already have a valid ISO 13485:2016 QMS certificate from a certification body,</i>				
<ul style="list-style-type: none"> - <i>In the "CAB" cell, enter the name of the certification body that issued your certificate.</i> - <i>In the "Expiration Date" cell, specify the date on which the certificate expires.</i> - <i>In the "Certification Scope" cell, write the scope exactly as it appears on the certificate.</i> 				
<input type="checkbox"/> The manufacturer is already certified to a QMS standard.		CAB:		Expiration Date:
Standard:		Certification Scope:		
<i>Mark this box if you already have a valid QMS certificate, other than ISO 13485 (ISO 9001, MSDAP...) from a certification body.</i>				
<ul style="list-style-type: none"> - <i>In the "CAB" cell, enter the name of the certification body that issued your certificate.</i> - <i>In the "Expiration Date" cell, specify the date on which the certificate expires.</i> - <i>In the "Standard" cell, write the standard or program (ISO 9001, MSDAP...) on which your certificate is based.</i> - <i>In the "Certificate Scope" cell, write the scope exactly as it appears on the certificate.</i> 				
<input type="checkbox"/> The manufacturer is already certified under MDR for different scope.		CAB:		Expiration Date:
Certification Scope:				
<i>Mark this box if you already have a valid MDR certificate for another device or group of devices from a Notified body.</i>				
<ul style="list-style-type: none"> - <i>In the "CAB" cell, enter the name of the notified body that issued your certificate.</i> - <i>In the "Expiration Date" cell, specify the date on which the certificate expires.</i> - <i>In the "Certificate Scope" cell, write the scope exactly as it appears on the certificate.</i> 				
<input type="checkbox"/> None of the above.				
<i>Mark this box if you don't have any certificates,</i>				
If suspended or withdrawn, please mention the reason.				

<i>If any of your previous certificates were suspended or withdrawn, provide the reason in here.</i>
If the certificate is still valid, please write the reason for changing the notified/ certification body.
<i>If you are applying for "Transfer" service for a valid MDR or ISO 13485 certificate (as marked in section 3 of this RFQ), , provide the reason for changing the notified body or certification body.</i>

6. Previous Applications	
Have you lodged an application in parallel with another notified body for the same conformity assessment procedure?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If you have signed a certification agreement with another notified body for the same scope (devices or services), mark "Yes". Otherwise mark "No".</i>	
Do you have an application refused by any notified body for the same conformity assessment you have lodged application?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide details:	
<i>If you have signed a certification agreement with another notified body, and they terminated your process and rejected your application, select "Yes." Otherwise, select "No."</i>	
<i>If you select "Yes," please provide the reason for rejection in the corresponding cell.</i>	
Have you withdrawn the application you have already submitted to another notified body prior to the decision of the notified body for the same conformity assessment you are applying for?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide details:	
<i>If you signed a certification agreement with another notified body for the same scope (devices or services) but withdrew it before the certification process was completed, select "Yes." Otherwise, select "No."</i>	
<i>If you select "Yes," please provide the reason for the withdrawal in the corresponding cell.</i>	

7. Conflict of Interests	
For devices and services given within this form, have you used or are you using a consultant to help you in your design, construction, marketing or maintenance of the products process or installation and maintenance of Quality Management System?	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes,	
Consultant Name:	e-mail:
<i>If you have used any kind of consultancy services for designing of device, setting up the manufacturing infrastructure, establishing and implementing QMS, preparation of technical documentation, trainings....., mark "Yes". Otherwise, mark "No".</i>	
<i>In case of "Yes", provide consultant name and e-mail address in corresponding cells.</i>	
For devices and services given within this form, have you used Notice d.o.o. services? (Excluding open trainings)	
<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide details:	
<i>If you have used any services from Notice d.o.o. (except public trainings) before, mark "Yes". Otherwise, mark "No".</i>	
<i>In case of "Yes", provide service details in corresponding cells.</i>	
Is there any connection/relationship between your organization and NOTICE testing subcontractors presented on www.notice.si?	

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide details:	
<ul style="list-style-type: none"> - Check the subcontractors list on our website: www.notice.si - In case there is any kind of relationship (personal/ commercial) between your company and NOTICE's subcontractors (e.g., being related to an employee, partially or totally owning the company, being involved in business relations, etc.), mark "Yes". Otherwise, mark "No". <p><i>In case of "Yes", provide the name(s) and relationship details in corresponding cell.</i></p>	

8. Devices Information (fill this section for each product separately)

Device Name	<i>Provide generic device name in here.</i>		
Trademark	<i>Write the trademark/brand used for the devices. If you don't have a trademark, write "N/A".</i>		
Models/Variants	<p><i>List the devices' models and/or variants, specifying the differences among them.</i></p> <p><i>Note:</i> <i>Model refers to the base version or primary configuration of a medical device. It shares the same core design, intended use, and fundamental characteristics of the device. but also includes a specific set of features and functionalities.</i></p> <p><i>Variant refers to a version or modification of a particular model. Variants share the core design and functionality of the original model but have some modifications or differences, such as in size, color, or minor features.</i></p> <p><i>For example:</i></p> <ul style="list-style-type: none"> - <i>Device: Surgical laser</i> <i>Model: Same intended use, different wavelength, or different output powers, etc.</i> <i>Variant: Same model, different handpiece, or different size, or different screen</i> - <i>Device: Intraarticular hyaluronic acid filler</i> <i>Model: Same intended use, different formulation, etc.</i> <i>Variant: Same model, different volumes</i> 		
Does it come in a set	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes, please define the contents of the set:			
<i>If your device is intended to be sold in a package⁶, as set, mark "Yes" and provide content of related package content with their CE marking status. Otherwise, mark "No".</i>			
Intended use	<i>Provide device's intended purpose⁷ as described in instruction for use (IFU) of your device with related indications (if any).</i>		
Mode of action	<i>Provide information on how your device achieves its intended purpose (by emphasizing the ways to achieve intended purpose by means of physical, chemical, pharmacological, immunological or metabolic, etc.).</i>		
Accessories	<i>Provide a list of all accessories associated with the device for which you are requesting MDR certification.</i>		
EMDN Code	<i>Provide device's EMDN code in here.</i>	MDA/MDN/MDS/MDT Code(s)	<i>Provide device's medical device code⁸ in here.</i>
Class	<i>Provide the risk class⁹ of device in here.</i>	Classification Rule	<i>Provide the applied rule¹⁰ for device's risk class in here.</i>
Basic UDI-DI	<i>Provide the basic UDI-DI of device in here.</i>		
Production Processes			
1.			4.

⁶ Based on the definitions in EU 2017/745 MDR Article 2 (10), (11) and the requirements of Article 22.

⁷ Based on the definitions in EU 2017/745 MDR Article 2 (12).

⁸ Based on the requirements of MDCG 2019-14.

⁹ Based on the requirements of EU 2017/745 MDR Annex VIII Chapter II and III.

¹⁰ Based on the requirements of EU 2017/745 MDR Annex VIII Chapter II and III.

2.	5.																
3.	6.																
<p><i>List all the processes used in manufacturing of the devices. You can also attach workflows, or any other documents providing information on the manufacturing processes. .</i></p>																	
Materials Used in the Final Product																	
1.	3.																
2.	4.																
<p><i>List of materials used in the device. You can also attach any supplementary document specifying the materials used in your device as supporting evidence.</i></p>																	
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:40%; padding: 5px;">Does the device incorporate:</th> <th style="width:10%; padding: 5px;">Yes</th> <th style="width:10%; padding: 5px;">No</th> <th style="width:40%; padding: 5px;">If yes, please name the substance.</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">medicine?</td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">tissues or cells of human origin, or their derivatives?</td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">tissues or cells of animal origin, or their derivatives?</td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align:center; padding: 5px;"><input type="checkbox"/></td> <td></td> </tr> </tbody> </table>		Does the device incorporate:	Yes	No	If yes, please name the substance.	medicine?	<input type="checkbox"/>	<input type="checkbox"/>		tissues or cells of human origin, or their derivatives?	<input type="checkbox"/>	<input type="checkbox"/>		tissues or cells of animal origin, or their derivatives?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the device incorporate:	Yes	No	If yes, please name the substance.														
medicine?	<input type="checkbox"/>	<input type="checkbox"/>															
tissues or cells of human origin, or their derivatives?	<input type="checkbox"/>	<input type="checkbox"/>															
tissues or cells of animal origin, or their derivatives?	<input type="checkbox"/>	<input type="checkbox"/>															
<p><i>Based on the composition of the device, indicate whether the device incorporates any medicinal substances, tissues or cells of human origin, or tissues or cells of animal origin, including their derivatives.</i></p> <p><i>If Yes, please clearly identify and list the relevant substance(s).</i></p> <p><i>For medicinal substances, declare any substance that qualifies as a medicinal product according to Directive 2001/83/EC, or any substance that, if used separately, would be considered a medicinal product under that Directive.</i></p> <p><i>For human- or animal-derived materials, include any tissues, cells, or their derivatives (e.g., collagen, hyaluronic acid, gelatine, albumin, growth factors, nucleotides) where the origin may be human or animal.</i></p> <p><i>If the origin of the substance may vary depending on the source, please specify the origin where known (e.g., synthetic, microbial fermentation, animal-derived, human-derived).</i></p> <p><i>Ensure that all relevant substances contained in the device, coating, or integral components are declared.</i></p>																	
Sterilization Status																	
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%; padding: 5px;"><input type="checkbox"/> Sterile</td> <td style="width:33%; padding: 5px;"><input type="checkbox"/> To be sterilized prior to use</td> <td style="width:33%; padding: 5px;"><input type="checkbox"/> Non-Sterile</td> </tr> <tr> <td style="padding: 5px;"><input type="checkbox"/> ETO</td> <td style="padding: 5px;"><input type="checkbox"/> Steam</td> <td style="padding: 5px;"><input type="checkbox"/> Radiation</td> </tr> <tr> <td style="padding: 5px;"><input type="checkbox"/> Dry Heat</td> <td style="padding: 5px;"><input type="checkbox"/> Hydrogen Peroxide</td> <td style="padding: 5px;"><input type="checkbox"/> Other (specify):</td> </tr> </table>		<input type="checkbox"/> Sterile	<input type="checkbox"/> To be sterilized prior to use	<input type="checkbox"/> Non-Sterile	<input type="checkbox"/> ETO	<input type="checkbox"/> Steam	<input type="checkbox"/> Radiation	<input type="checkbox"/> Dry Heat	<input type="checkbox"/> Hydrogen Peroxide	<input type="checkbox"/> Other (specify):							
<input type="checkbox"/> Sterile	<input type="checkbox"/> To be sterilized prior to use	<input type="checkbox"/> Non-Sterile															
<input type="checkbox"/> ETO	<input type="checkbox"/> Steam	<input type="checkbox"/> Radiation															
<input type="checkbox"/> Dry Heat	<input type="checkbox"/> Hydrogen Peroxide	<input type="checkbox"/> Other (specify):															
<p><i>Mark sterility condition of the device.</i></p> <p><i>If you sterilize the device prior placing on the EU market, mark “Sterile”.</i></p> <p><i>If you don’t sterilize the device prior placing on the EU market but it is intended be sterilized by user prior to use, mark “To be sterilized prior to use”.</i></p> <p><i>Otherwise, mark “Non-Sterile”.</i></p> <p><i>If device is intended to be placed on the market in one of “Sterile” or “To be sterilized prior to use” conditions, mark related sterilization method.</i></p>																	
Packaging																	
Number of packages:	Material:																
<p><i>Provide information on the number of packages and their material for the sterile barrier system in corresponding cells. In case of multiple sterile packages, provide the order with number of packages.</i></p>																	
Cleanrooms																	

Location (Address)		Number of cleanrooms in the location
<i>Provide the address of your cleanrooms in here.</i>		<i>Provide the number of rooms located in the related address with their cleanliness class.</i>
Contact Status of a Single Device (EN ISO 10993-1)		
Mark relevant contact characteristics (contact type, contacting structures, contact duration, exposure characteristics) given below by taking the give descriptions and examples into consideration.		
<input type="checkbox"/> Contact (indicate contact type, exposure characteristics and contact duration)		<input type="checkbox"/> Non-contact
<i>Contacting medical devices are medical devices (or components) which have either direct contact or indirect contact</i>		
<i>Direct contact means physical contact of a medical device (or component), with tissue including circulating blood</i> <i>Examples of medical devices with direct contact, devices used to collect a tissue sample, such as needles, scalpels or lancets are considered to be body contacting.</i>		
<i>Indirect contact means no physical contact of a medical device (or component) with tissue but having contact with a fluid (liquid or gas), semi-solid or solid substances/materials which is intended to come in contact with tissue.</i> <i>Examples of medical devices with indirect contact, devices used to store a tissue sample or body fluid, that is intended to have subsequent body contact, such as organ perfusion systems, are considered to have indirect contact with the body.</i>		
<i>Non-contacting medical devices are medical devices (or components) which have neither direct contact nor indirect contact with the body.</i> <i>Examples of non-contacting devices: Diagnostic software, X-ray generators used for medical imaging, etc.</i>		
<i>The following section shall be filled in, if "Contact" box is checked for "Contact Status" part.</i>		
<input type="checkbox"/> Intact Skin	<input type="checkbox"/> Intact Mucosal Membrane ¹¹	<input type="checkbox"/> Circulating Blood
<i>Medical devices in contact with intact skin are medical devices which have only direct contact or indirect contact with intact, uncompromised skin.</i> <i>Examples: Electrodes, external prostheses, fixation tapes and compression bandages.</i>	<i>Medical devices in contact with intact mucosal membrane are surface-contacting medical devices having direct contact or indirect contact with intact mucosal membranes.</i> <i>Examples: Contact lenses, urinary catheters, intravaginal and intra-intestinal devices (stomach tubes, sigmoidoscopes, colonoscopes, gastroscopes), endoscopic irrigation systems and tubing, endotracheal tubes, bronchoscopes, some dental prostheses and orthodontic devices.</i>	<i>Medical devices having direct contact or indirect contact with circulating blood, including medical devices that store blood for human use or act as conduits to deliver fluids to or from blood.</i> <i>Examples:</i> <i>1- solution administration sets, extension sets, transfer sets and blood administration sets,</i> <i>2- temporary pacemaker electrodes, oxygenators, haemoadsorbents and immunoadsorbents.</i> <i>3- Medical devices with components that are internal and external to the body, such as intravascular catheters or delivery systems, extracorporeal oxygenator tubing and accessories, dialysers, and dialysis tubing and accessories.</i> <i>4- Components of pacemaker electrodes and leads within the cardiovascular system, artificial arteriovenous fistulae, heart valves, vascular grafts, prostheses and stents, internal drug-delivery catheters, vascular and cardiac implants, and ventricular assist devices</i> <i>This category is not intended to include devices only in contact with bleeding tissue (e.g. a hernia repair graft), which should be categorized as having contact with internal tissues</i>

¹¹ A mucous membrane (or mucosa) is a moist layer of tissue that lines the body cavities and canals that are exposed to the external environment. This includes respiratory tract (nose, mouth, throat, lungs), digestive tract (mouth, esophagus, stomach, intestines, rectum), urogenital tract (urethra, bladder, vagina, uterus).

<input type="checkbox"/> Internal Tissues (other than circulating blood)		<input type="checkbox"/> Breached or compromised surface (skin or mucosal membrane)	
<p>Medical devices with direct contact or indirect contact with bone, dentin, internal soft tissues or organs; Examples: 1- Medical devices that contact tissue, bone or pulp/dentin including laparoscopes, arthroscopes, draining systems, dental filling materials, skin staples, wires and biopsy needles. 2- Medical devices that have indirect contact by serving as conduits to store or deliver fluids to bone or tissues, including tubing sets used for irrigation, infusion or drainage. 3- Medical devices that contact bone including orthopaedic pins, plates, joint prostheses, bone cements and intraosseous devices. 4- Medical devices that contact soft tissues and tissue fluids including pacemakers, drug delivery devices, neuromuscular sensors and simulators, replacement tendons, breast implants, artificial larynxes, subperiosteal implants, ligation clips and intrauterine devices that do not achieve their primary function by chemical activity.</p>		<p>Surface contacting medical devices having direct contact or indirect contact with breached or compromised surfaces (skin or mucosal membranes). Examples: Dressings or healing devices, occlusive patches for ulcers, burns and granulation tissue and wound cleansing and irrigation devices.</p>	
Does it come in contact with heart or central circulatory system?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Mark "Yes", if your device comes in contact with heart or central circulatory system (means following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)</p> <p>Otherwise, mark "No". if your device comes in contact with central nervous system (means the brain, meninges and spinal cord).</p>			
Does it come in contact with central nervous system?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Mark "Yes", if your device comes in contact with central nervous system (means the brain, meninges and spinal cord).</p> <p>Otherwise, mark "No".</p>			
<p>The following section shall be filled in, if "Contact" box is checked for "Contact Status" part.</p>			
Exposure Characteristics			
<input type="checkbox"/> Daily Contact	<input type="checkbox"/> Intermittent Contact	<input type="checkbox"/> Bioaccumulation	
<p>Daily contact is when a medical device contacts the body every day for any portion of a day. Examples: 1- A continuous positive airway pressure (CPAP) machine which is used every day for five hours per day for a lifetime, 2- A single use disposable feeding tube set used with a feeding pump system is replaced multiple times in a single patient over the period of treatment (e.g. two hours of use every day for 10 days or two hours of use every day for more than 30 days).</p>	<p>Intermittent contact is the use of the device where there is a period of at least 24 hours between consecutive tissue contacts. This type of contact can be for the repeated use of one medical device or a replacement of the same medical device under consideration. Examples: 1- Medical devices used a few times a year (e.g. one hour treatment period, every six months for a maximum of three years) 2- Medical devices used for repeated treatment sessions (e.g. one hour treatment period, once every three weeks for a total of up to 10 sessions)</p>	<p>Bioaccumulation is the gradual accumulation of a substance into human body. The potential for bioaccumulation of medical device constituents shall be considered for all duration categories. Where bioaccumulation is expected (e.g. a raw material contains perfluoro-heptanoic acid, a substance known to bioaccumulate in humans)</p>	
Cumulative Exposure per Patient (to be defined in case of daily or intermittent contact)		<p>Write the longest possible treatment period that your device might be used. For example, 1- periods like "for a lifetime", "for 10 days", and "for more than 30 days" in the examples provided for "Daily Contact"; 2- periods like "every six months for maximum 3 years" and "once every three weeks for up to 10 sessions" in the examples provided for "Intermittent Contact";</p>	

		<i>are considered as cumulative exposure period.</i>
<i>The following section shall be filled in, if "Contact" box is checked for "Contact Status" part.</i>		
Contact Duration		
<input type="checkbox"/> < 1h	<input type="checkbox"/> 1h > <24h	<input type="checkbox"/> > 24h
<input type="checkbox"/> 24h >... <30d	<input type="checkbox"/> > 30d	
Invasiveness	<input type="checkbox"/> Invasive (indicate contact type)	<input type="checkbox"/> Non-invasive
<input type="checkbox"/> Body Orifice	<input type="checkbox"/> Surgically Invasive	
<i>Taking the following definitions into consideration, mark invasiveness status of the device. If you choose "Invasive", select if it penetrates through "body orifice" or "surgical" methods.</i>		
<i>"Invasive device" means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;</i>		
<i>"Body orifice" means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.</i>		
<i>"Surgically invasive device" means:</i>		
<i>(a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and</i>		
<i>(b) a device which produces penetration other than through a body orifice.</i>		
<i>If the device is not invasive, mark "Non-invasive".</i>		
Other specific device characteristics		
Incorporates medicine?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please name the substance:		
Incorporates human blood/ human plasma?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Incorporates tissues or cells of human or animal origin, or their derivatives?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device reusable?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Incorporates or consists of nanomaterial ¹² ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the product composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the product utilize biologically active coating?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the device incorporate software?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Measuring function?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device intended to administer and/or remove a medicinal product?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the software drive the device /influences the use of a device?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is there any vigilance reporting related to the product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please provide details:		

¹² Nano material: a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

Has there been any recall decision regarding your products?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please provide details:		
Is the device an orphan device?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please provide justification:		
Is the device a breakthrough device ¹³ ?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please provide justification:		
<p><i>If any of the above questions applies to the device, mark "Yes". Otherwise mark "No". For some questions, provide further details under the corresponding question regarding the specific characteristics.</i></p>		
Device tests		
Have the device tests been performed internally?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, please provide information of testing facilities	1.	4.
	2.	5.
	3.	6.
<p><i>Provide information on testing process of the device. If the testing is performed internally by your organization, mark "Yes". Otherwise, mark "No". In case of "No", provide the list of testing facilities that conducted the testing.</i></p>		
Requested MDR Conformity Assessment Procedure for the Device		
<input type="checkbox"/> Annex IX		<input type="checkbox"/> Annex XI Part A
<p><i>For the specific device covered by this table, indicate the conformity assessment procedure you wish to follow for certification.</i></p>		

9. Documents to be submitted together with this form
<ol style="list-style-type: none"> 1. Business License 2. Product IFU, Catalogue or other informational material 3. Previous CE & QMS Certificates 4. In case of requesting Production quality assurance certificate according to Annex XI, Part A, for class IIb and III devices, an EU type examination certificate according to Annex X 5. Latest balance sheet * 6. Official document indicating the number of employees* (Including (a) employees; (b) persons working for the enterprise being subordinated to it and deemed to be employees under national law; (c) owner-managers; (d) partners engaging in a regular activity in the enterprise and benefiting from financial advantages from the enterprise. Apprentices or students engaged in vocational training with an apprenticeship or vocational training contract are not included as staff. The duration of maternity or parental leaves is not counted.) <p>* Submission of documents stipulated in 5 & 6 is optional. The information is requested in order to decide if the company falls into micro, small & medium size category to determine whether the related discount can be applied</p>

¹³ A MD will be considered a breakthrough device if it meets each of the following criteria:

1. Novelty: The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice, AND 2. Positive clinical impact: The device is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

- Offering a significant positive clinical impact on patients or public health compared to available alternatives and the state of the art, OR
- Fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

Please attach the documents specified in items 1-4 to the RFQ and submit them to NOTICE. These documents are **mandatory**, and your RFQ will not be evaluated if any of them are missing.

Additionally, if you would like to benefit from the discount available for SMEs (Small and Medium Enterprises), please submit items 5 and 6. This will allow us to assess whether your business qualifies as an SME.

10. Approval (The correctness of the provided information is confirmed by the signer.)

By signing this form, I consent to the collection, processing, and storage of my personal data by Notice d.o.o., in accordance with the General Data Protection Regulation (GDPR) and Notice's terms & conditions. I understand that my data will be used for the purpose of processing my application, communication and providing services, and that I have the right to withdraw my consent at any time by contacting gdpr@notice.si.

Authorized Person*:	Position:
Pertinent organization <input type="checkbox"/> Manufacturer	<input type="checkbox"/> Authorized Representative
Date:	Signature:

* The form shall be signed by an authorized signatory of the manufacturer or its EU representative.

Fill in this table and sign it.

Contact Information

NOTICE d.o.o.

Room 207, 208, World Trade Centre, Dunajska cesta 156, 1000
Ljubljana – Slovenia

Email: info@notice.si

Website: www.notice.si

