Notice of change in the product or in the management system

Please fill the questionnaire in the electronic form, sign and return to the email mdd@siq.si.

Information about organization

Organization:	
Address:	
Contact person:	

Product details

Number of the EC certificate:	
Product category:	
Product name:	
Model/Type:	

Change

The cause of the change:	
Description of the change:	

The change affects

The process of product realization:		YES		NO
Function of the product:		YES		NO
Performance of the product:		YES		NO
Usability of the product:		YES		NO
Safety of the product:		YES		NO
Applicable regulatory requirements:		YES		NO

Mark with X

Location

Change of organization location:		YES		NO
Change of production place:		YES		NO

Address of the new location:	

Other changes

Technical and/or quality management systems documentation

Change in the technical documentation and/or quality management system documentation:		YES		NO

If you answered YES, please complete the following:

Name of the previous document, version and date:	Name of the revised document, version and date:
1.	1.
2.	2
3.	3.

Additional notes

Place: _____

Date: _____ _____

Signature

Completed by SIQ, Ljubljana

The following documentation have been changed

	Topic	Comments
	Essential Requirements	
	Clinical Evaluation Report	
	Risk analysis	
	Biocompatibility	
	Software	
	User Manual	
	Declaration of Conformity	
	Other:	

Mark with X

Notified Body activities

		Comments
	Post audit is not needed	
	The object of changes shall be reviewed at next surveillance or recertification audit	
	Post audit of technical documentation	
	Post audit on site of the location	

Mark with X

Additional notes

Place: _____

Date: _____ _____

Signature