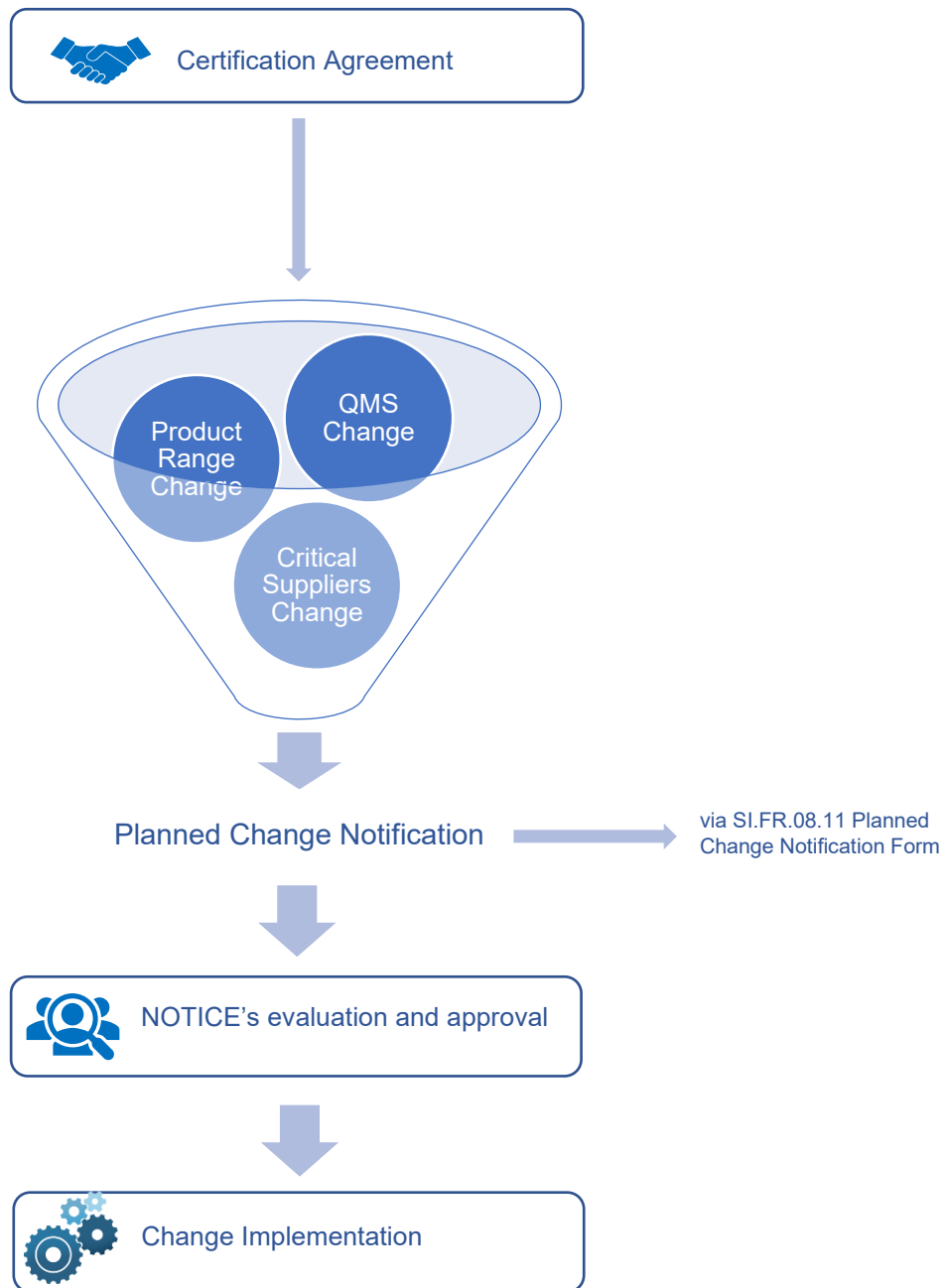


After signing the Agreement (SI.FR.23.01 Certification Proposal/ Agreement), all the planned changes in the client's quality management system or the products shall be communicated to NOTICE via SI.FR.08.11 Planned Change Notification Form which is available on our website.

All the planned changes shall be assessed and approved by NOTICE before they can be implemented by the client.



Changes to be communicated to NOTICE can include, but not limited to:

Changes	to the approved quality management system or systems or to the product range covered,
	in company's legal status,
	in the company's key personnel,
	in the manufacturing address and locations,
	in address notation,
	in the company's critical suppliers,
	in product design,
	in product raw materials,
	in the use or intended use of the product,
	in the approved type of a device,
	in instructions for use and label,
	in critical processes,
	in technical documentation.

SI.FR.08.11 Planned Change Notification Form (available on our website) shall be filled in by the manufacturer for all the planned changes before their implementation. Followings shall be specified in the form;

- Type of change,
- The status of the change subject before and after the change,
- The reason of change together with the documents affected by the change.

The form shall be submitted to NOTICE along with the documents necessary to justify the change.

As a result of the evaluation, additional reviews and/or site audits can be conducted. The reviews/audit fees will be charged additionally.

### **Contact Information**

NOTICE d.o.o.

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

**Email:** [info@notice.si](mailto:info@notice.si)

**Website:** [www.notice.si](http://www.notice.si)

