

# Supplier Checklist

**Scope / Purpose** This checklist is completed every time an initial supplier evaluation is carried out or if a blocked supplier is evaluated again for approval.

## 1. General Supplier Information

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Company Name	OpenReg GmbH
Address:	c/o Factory Works GmbH Rheinsberger Str. 76/7710115 Berlin Germany
Point of Contact (job role, email, phone):	(...)

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## 2. Purchase Description

NOTE: enter here a description of the goods and services the organization intends to typically purchase from this supplier.

Quality Requirements:

- <enter text>

NOTE: enter here requirements based on which you will assess the supplier as part of your continuous supplier surveillance. For example: server uptime (for cloud server providers), bugs resulting from development (for development providers).

## 3. Supplier Criticality

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Criticality Criteria	Yes / No	Explanation / Commentary
(1.) Could the purchased goods or services have a <b>direct</b> impact on the <b>safety</b> of the organization's medical devices?		
(2.) Could the purchased goods or services have an <b>indirect</b> impact on the <b>safety</b> of the organization's medical devices?		
(3.) Could the purchased goods or services have a <b>direct</b> impact on the <b>performance</b> of the organization's medical devices?		
(4.) Could the purchased goods or services have an <b>indirect</b> impact on the <b>performance</b> of the organization's medical devices?		

Criticality Criteria	Yes / No	Explanation / Commentary
(5.) Could the purchased goods or services have a <b>direct</b> impact on the <b>regulatory compliance</b> of the organization's medical devices?		
(6.) Could the purchased goods or services have an <b>indirect</b> impact on the <b>regulatory compliance</b> of the organization's medical devices?		
(7.) Is the organization not able to manufacture medical devices without the supplier's goods or services?		
(8.) Is this the only available supplier for these goods or services?		

- A supplier is classified as **critical** if the supplier **directly** impacts either safety, performance or regulatory compliance, or both (7.) and (8.) are answered with YES.
- A supplier is classified as **non-critical** if all the questions (1.) and (3.) and (5.) are answered with NO.
- The QMO decides over criticality on a case-by-case basis, if the questions (1.) and (3.) and (5.) and both (7.) and (8.) are answered with NO, but one of the questions on indirect impact (2, 4, 6) are answered with YES.

**Assessment of Criticality:** <enter here>

(The assessment result is added to the List of Qualified Suppliers)

#### 4. Supplier Evaluation

Evaluation Criteria	Score	Explanation / Commentary
Quality of Products/Services		
Timeliness / Punctuality		
Cooperation		
Payment Terms		

Average score:

Provisions for supplier evaluation and further information can be found in step 1.4 of the organization's supplier process.

Additional evaluation criteria can be used to evaluate the suppliers:

Further Criteria	Yes / No	Explanation / Commentary
Is there a non-disclosure agreement (NDA) in place between the supplier and our organization?		
Does the supplier have a certified management system in place?		<e.g. ISO 9001, ISO 13485>
Does the supplier conduct quality reviews before shipment?		
Does the supplier have a system for traceability established?		
Does the supplier have a procedure for the handling of nonconforming products in place?		
Does the supplier have a procedure for the corrective and preventive actions in place?		
Does the supplier have a procedure in place to notify customers of changes?		
Does the supplier further subcontract the services/products concerned and does the supplier have its own supplier evaluation process in place?		

**Additional supplier information / description:**

<enter additional information>

Final Evaluation Result	Yes / No	Explanation / Commentary
Does the supplier comply with the organization's quality requirements?		

(The evaluation result is added to the List of Qualified Suppliers)

Evaluation Completed By:	<enter name and job role>
Date Completed:	<enter date>

**5. Surveillance Measures**

Surveillance Measures	Yes / No	Explanation / Commentary
Is the supplier required to provide proof of certification?		
Is the supplier required to enter a quality assurance agreement (QAA)?		
Is the supplier required to agree to a supplier audit program?		
Are any other supplier surveillance measures required?		

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