



COMPLAINT FORM

CONFIDENTIAL COMPLAINT INVESTIGATION

Registration No:	Registration Date:	Pages
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Instructions

PLEASE NOTE! The blue sections are filled out by the reporter/customer, green sections by Bio-Works.

Send the form to: complaints@bio-works.com
Sales Department
Telephone: +46 8 562 67 430

Important information regarding shipment goods etc.

If applicable, shipping details will be provided when your complaint has been investigated.

You will receive a confirmation of the complaint and when the investigations are finalized, you will receive the final report.

The below sections in blue are used by the reporter/customer

CONTACT INFORMATION

Company / Customer / Distributor	
Name:	E-mail:
Address:	Telephone number:
City/Country:	Today's date:
Other information:	Delivery date:

COMPLAINT CLASSIFICATION

Mark at least one option		
<input type="checkbox"/> Delivery	<input type="checkbox"/> Packaging	<input type="checkbox"/> Function

PRODUCT TYPE

Product group		
<input type="checkbox"/> WorkBeads bulk resin	<input type="checkbox"/> OptioBio	<input type="checkbox"/> BabyBio
Product Type	Volume - bulk	Size - column
<input type="checkbox"/> Size Exclusion	<input type="checkbox"/> 1-25 ml	<input type="checkbox"/> 1 ml
<input type="checkbox"/> Ion Exchange	<input type="checkbox"/> 50-300 ml	<input type="checkbox"/> 5 ml
<input type="checkbox"/> Protein A affinity	<input type="checkbox"/> 1L	<input type="checkbox"/> Kit
<input type="checkbox"/> IMAC	<input type="checkbox"/> >1L	<input type="checkbox"/> Other
Article no:	Batch/ID no:	
Other		



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DESCRIPTION

What has happened?
Other information or questions

The below sections in green are used by the company when handling the complaint

REGISTRATION

Registration made by:	Acknowledge Date:

EVENT EVALUATION

Event Evaluation		
Classified as Critical Issue	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If YES, reason and action:		
Risk analysis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Recall product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Replace product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Quality Action Identity:	Quality Action Responsible:	
Review date:	Review Responsible:	

INVESTIGATION

Root Cause Identification

Identification of Root Cause		
<input type="checkbox"/> New Problem	<input type="checkbox"/> Known Problem	<input type="checkbox"/> N/A
<input type="checkbox"/> Routines not followed, training needed	<input type="checkbox"/> Routines not appropriate, issue change request	<input type="checkbox"/> No actions, complaint can be closed
Description:		



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Corrective Actions and Preventive Actions

Corrective Actions Completed/Ongoing/Planned	
Finish date:	Responsible:
Preventive Actions Completed/Ongoing/Planned	
Finish date:	Responsible:

Risk Assessment and Final Classification

Implications on Risk Management File		
Implications on Risk Management	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Risk Management Log No:	Initiation Date:	
Date:	Signature Investigator:	

INTERNAL CLOSURE (Product Manager)

Closure		
Planned action(s) implemented?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Implemented action(s) effective/sufficient?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Field corrective action (FCA) required	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Date:	Signature PM:	

CLOSURE CONFIRMATION (COMPANY CONTACT)

Company Contact Confirmation		
Complaint closing accepted?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If NO, reason:		
Date:	QA Responsible:	