

Bunzl Healthcare Medical Device Report Form

Fields marked * are mandatory for a successful investigation

Internal Use Only

Bunzl Healthcare use only

*Name of Reporter: Click here to enter text.	Sales Representative: Click here to enter text.	*Date form completed: Click here to enter a date.
*Contact method: Email <input type="checkbox"/> Telephone		

Customer / Complainant Details		
<i>Institute / Hospital / Clinic / Company</i>	<i>Contact Person / Complainant</i>	
*Name of above: Click here to enter text.	*Contact Name: Click here to enter text.	
*Department: Click here to enter text.	*Email: Click here to enter text.	
*Address: Click here to enter text. Click here to enter text. Click here to enter text. Click here to enter text.	*Phone: Click here to enter text.	Fax: Click here to enter text.
	Complaint Source: Bunzl Healthcare <input type="checkbox"/> Employee <input type="checkbox"/> Distributor Customer <input type="checkbox"/> End User <input type="checkbox"/> MHRA <input type="checkbox"/> If end user, please provide Job Title: Click here to enter text.	

Product information		
*Product Code: Click here to enter text.	*Product Description (include pack size): Click here to enter text.	*Lot / Batch: Click here to enter text.
Pharmaceutical Form: Click here to enter text.	Strength: Click here to enter text.	Expiry Date: Click here to enter text.
Number of identical events with the same Lot/Batch Number: Unknown <input type="checkbox"/> If known please specify number: Click here to enter text.		
*Is the sample available? No <input type="checkbox"/> Yes, not contaminated <input type="checkbox"/> Yes, contaminated <input type="checkbox"/> Photo Evidence Only <input type="checkbox"/>		Defective Quantity to return: Click here to enter text.
		Date Returned: Internal use only

**** WE REQUIRE A COMPLETED DECONTAMINATION CERTIFICATE BEFORE AUTHORIZING THE RETURN OF USED SAMPLES ****

Event Description
*Please provide a full detailed description: Click here to enter text

Procedure name: Click here to enter text.	Procedure / Date: Click here to enter a date.
Procedure Outcome: Completed with this device/pack <input type="checkbox"/> Completed with another device/pack <input type="checkbox"/> Completed with a different device/pack <input type="checkbox"/> Aborted due to this event <input type="checkbox"/> Aborted due to same device/pack unavailable <input type="checkbox"/> No information available <input type="checkbox"/> Aborted due to another reason <input type="checkbox"/> Reason: Click here to enter text.	
Time of event: Unpacking <input type="checkbox"/> Preparation <input type="checkbox"/> Introduction <input type="checkbox"/> During Procedure <input type="checkbox"/> Withdrawal <input type="checkbox"/> Procedure Closure <input type="checkbox"/> Post Procedure <input type="checkbox"/> No information available <input type="checkbox"/>	
*Did the event lead to complications for the user or patient which required medical intervention? *1 No <input type="checkbox"/> Yes <input type="checkbox"/> If Yes, User <input type="checkbox"/> Patient <input type="checkbox"/>	
*If Yes, please provide details of methods of medical intervention required: Click here to enter text.	
Competent Authority Notified? *2 No <input type="checkbox"/> Yes <input type="checkbox"/> If yes reported by: Customer <input type="checkbox"/> Bunzl Healthcare <input type="checkbox"/>	Date reported: Click here to enter a date.
Competent Authority Reference: Click here to enter text.	
Labour Standards Concern? Yes <input type="checkbox"/> No <input type="checkbox"/>	

If the answers to 1 and 2 are yes and no, this complaint will be treated with priority and the TQRM will be consulted to decide if the competent authority needs to be notified.

Please forward the completed Medical Device Report Form along with any samples as soon as possible to:
 Quality Assurance, Bunzl Healthcare, Boundary House, Interlink Way East, Coalville, Leicestershire, LE67 1 LA
 Email: ga.healthcare@bunzl.co.uk