Bunzl Healthcare Medical Device Report Form

Fields marked * are mandatory for a successful investigation

Internal Use Only

Bunzl Healthcare use only

*Name of Reporter:	Sales Representative:	*Date form completed:
Click here to enter text.	Click here to enter text.	Click here to enter a date.

*Contact method:

Email ☐ Telephone

Customer / Complainant Details

Institute / Hospital / Clinic / Company	*Contact Person / Complainant*	
***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 ☐ Employee ☐ Distributor Customer ☐ End User ☐ MHRA ☐ If end user, please provide Job Title: Click here to enter text.	

Product information

*Product Code:	*Product Description (include pack size):	*Lot / Batch:
Click here to enter text.	Click here to enter text.	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 ☐ If known please specify number: Click here to enter text.

*Is the sample available? No ☐ Yes, not contaminated ☐ Yes, contaminated ☐ Photo Evidence Only ☐	Defective Quantity to return: Click here to enter text.
	Date Returned: Internal use only

**** WE REQUIRE A COMPLETED DECONTAMINATION CERTIFICATE BEFORE AUTHORISING 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 ☐ Completed with another device/pack ☐ Completed with a different device/pack ☐

Aborted due to this event ☐ Aborted due to same device/pack unavailable ☐ No information available ☐

Aborted due to another reason ☐ Reason: Click here to enter text.

Time of event:

Unpacking ☐ Preparation ☐ Introduction ☐ During Procedure ☐ Withdrawal ☐ Procedure Closure ☐ Post Procedure ☐

No information available ☐

***Did the event lead to complications for the user or patient which required medical intervention?** [*1] No ☐ Yes ☐

If Yes, User ☐ Patient ☐

***If Yes, please provide details of methods of medical intervention required:**

Click here to enter text.

Competent Authority Notified? [*2] No ☐ Yes ☐ If yes reported by: Customer ☐ Bunzl Healthcare ☐	**Date reported**: Click here to enter a date.

Competent Authority Reference: Click here to enter text.

Labour Standards Concern? Yes ☐ No ☐

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: qa.healthcare@bunzl.co.uk