

Ref No	Rev No.	Issue Date

Incident Report

1. Administrative information	
Recipient	
Name of national competent authority (NCA)	
Address of national competent authority	
Date of this report	
Reference number assigned by the manufacturer	
Reference number assigned by NCA	
Type of report ☐ Initial report ☐ Follow-up report ☐ Combined initial and final report ☐ Final report	
Does the incident represent a serious public health threat? ☐ Yes ☐ No	
Classification of incident ☐ Death ☐ Unanticipated serious deterioration in state of health ☐ All other reportable incidents	
Identify to what other NCAs this report was also sent	

2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Others (identify the role):

This is an example of some points only , so the manufacturer can increase or change this points regarding manufacturing process