

Qualitätsmanagement-Handbuch Incident questionnaire

Kapitel 8

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CAPA / REP-No.: (This number is registered by the NOUV.)	AG)			
The following information on the incident is required in order to comply with a statutory reporting obligation: Please fill in the bank spaces completely and send the report to: NOUVAG AG E- Mail: complaint@nouvag.com				
Name:	Date:	Sign:		
Details of the product				
Product Name				
Item number on Product/ Packaging				
Manufacturer				
LOT/ Serial Nummer				
UDI				
Number of units				
Details of the creator of the complaint				
Client-No.				
Name/Company				
Contact person				
Street/Number				
Zip Code/Residence				
Phone number				
E-Mail				
Details of the complaint (incident)				
Details of the complaint (incident)	_			
Defect detection	☐ Before shipping☐ Before application☐ After application	☐ After shipping☐ During application☐ Not known		
Did the event affect patients,	Yes, fill in under "description of the event"			
users, or third parties?				
assis, s. a.ma panassi	☐ No	☐ Not known		
Description of the event (e.g. attach images as an attachment)				
Is the product available for defect analysis?	Yes No	☐ Not known		
Has an authority been notified?	☐ Yes ☐ No If "Yes", enclose a copy of the authority (attachments)	☐ Not known ne report to the		
Attachments: (e.g., copy of the report to the authority, pictures, etc.)				

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