

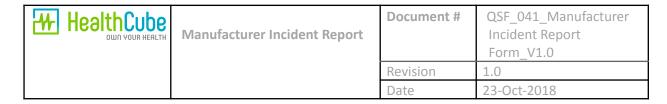
Document #	QSF_041_Manufacturer
	Incident Report
	Form_V1.0
Revision	1.0
Date	23-Oct-2018



Quality Management System Level III

QSF_041_Manufacturer Incident Report Form Version 1.0

Effective Date -23-Oct-2018



Review and Approval By

	Name	Designation	Signature	Date	
		Lead Engineer -			
Author	Priyanka BR	Quality &	PBR	23-Oct-2018	
		Regulatory Affairs			
	Reviewed By Licy Rajendra Prasad	Quality Engineer-			
Davisoned Do		Quality &	LRP	23-Oct-2018	
Reviewed By		Regulatory			
		Affairs			
Annuaria d Dec	Marrie Trice di	Head - Quality &	VT	22.04.2010	
Approved By	Varun Trivedi	Regulatory	VT	23-Oct-2018	

REVISION HISTORY

Rev # Effective Date		Description of Change
1.0	23-Oct-2018	Initial Release



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REPORT FORM MANUFACTURER'S INCIDENT REPORT

(Medical Devices Vigilance System MEDDEV 2.12/1 rev 8)

1. Administrative information			
Recipient			
Name of National Competent Authority (NCA)			
r			
Address of National Competent Authority			
radioss of rational competent rationty			
Date of this report			
Date of this report			
D.C			
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			
Final report			
D d 1 11 1 11 1 10 0			
Does the incident represent a serious public health threat?			
Yes			
No			
Classification of incident			
Death			
Unanticipated serious deterioration in state	e of health		
All other reportable incidents	e of neutin		
All other reportable incidents			
71 10 1 1 2701 11			
Identify to what other NCAs this report was also sent:			
2. Information on submitter of the report			
Status of submitter			
Manufacturer			
Authorised Representative within EEA			
Others (identify the role):			
outers (ractify the fole).			
2 Manufactures information			
3. Manufacturer information			
Name			
Contact person name			
Address			
Postal code	City		



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Phone	Fax		
E-mail	Country		
4. Authorised Representative information			
Name			
Contact person name			
Address			
Postal code	City		
Phone	Fax		
E-mail	Country		
5. Submitter's information (if different from section 3	or 4)		
Name			
Contact person name			
Address			
Postal code	City		
Phone	Fax		
E-mail	Country		
6. Medical device information			
Classification Class I Class II A Class II B Class III Active implantable device	IVD Annex II List A IVD Annex II List B IVD Devices for self-testing Other IVD device		
Nomenclature system (preferable GMDN)	Nomenclature code		
Nomenclature text			
Commercial name / brand name / make			
Model number	Catalogue number		
Serial number(s) (if applicable)	Lot / batch number(s) (if applicable)		
Software version number (if applicable)			
Device Manufacturing date	Expiry date		
Implant date (for implants only)	Explant date (for implants only)		
Duration of implantation (to be filled is the exact implant or explant dates are known)			



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Accessories / associated device (if applicable)			
Notified Body (NB) ID-number			
7. Incident information			
User facility report reference number (if applicable)			
Manufacturers awareness date			
Date the incident occurred			
Incident description narrative			
Number of patients involved (if known)	Number of medical devices involved (if known)		
Medical device current location / disposition (if known)			
Operator of the medical device at the time of incident (sell health care professional other	ect one) patient		
Usage of the medical device (indicate) initial use reuse of a single use medical device reuse of a reusable medical device re-serviced / refurbished problem noted prior use other (please specify)			
8. Patient information Patient outcome.			
Remedial action taken by the healthcare facility relevant t	o the care of the patient.		
Age of the patient at the time of incident (if applicable)			
Gender (if applicable) Female Male			
Weight in kilograms (if applicable)			
9. Healthcare facility information			
Name			
Contact person within the facility			



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Address			
Postcode	City		
Phone	Fax		
E-mail	Country		
10. Manufacturer's preliminary comments (Initial / Fo	ollow-up report)		
Manufacturer's preliminary analysis.			
Initial corrective actions / preventive actions implemented	l by the manufacturer:		
Expected date of next report:			
11. Results of manufacturers final investigation (Final	report)		
The manufacturer's device analysis results.			
Remedial action / corrective action / preventive action / F	ield Safety Corrective Action:		
NOTE: In the case of a FSCA the submitter needs to send	Field Safety Notice		
Time schedule for the implementation of the identified ac	tions:		
Final comments from the manufacturer:			
Further investigations:			
Is the manufacturer aware of similar incidents with this ty	Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?		
Yes N	o		
If yes, number of similar incidents:			
If yes, indicate in which countries and the report reference	e numbers of the incidents:		
For Final Report only. The medical device has been distributed to the following countries:			
□ All EEA States or specific states: □ AT □ BE □ BG □ CH □ CY □ CZ □ DE □ DK □ EE □ ES □ FI □ FR □ GR □ HR □ HU □ IE □ IS □ IT □ LI □ LT □ LU □ LV □ MT □ NL □ NO □ PL □ PT □ RO □ SE □ SI □ SK □ TR □ UK			
Other country (please specify):			
12. Comments:			



Signature			
Name	 Position		

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.