HealthCube
OWN YOUR HEALTH

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
Author	Priyanka BR	Lead Engineer - Quality & Regulatory Affairs	PBR	23-Oct-2018
Reviewed By	Licy Rajendra Prasad	Quality Engineer- Quality & Regulatory Affairs	LRP	23-Oct-2018
Approved By	Varun Trivedi	Head - Quality & Regulatory	VT	23-Oct-2018

REVISION HISTORY

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

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)	
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 ☐ Authorised Representative within EEA ☐ Others (identify the role):	
3. Manufacturer information	
Name	
Contact person name	
Address	
Postal code	City

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)	

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 (select one) ☐ health care professional ☐ patient ☐ other	
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 to 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	

Address	
Postcode	City
Phone	Fax
E-mail	Country

10. Manufacturer's preliminary comments (Initial / Follow-up report)

Manufacturer's preliminary analysis.

Initial corrective actions / preventive actions implemented 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 / Field 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 actions:

Final comments from the manufacturer:

Further investigations:

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

☐ Yes ☐ No

If yes, number of similar incidents:

If yes, indicate in which countries and the report reference 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.