10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

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

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? ALBANIA, AUSTRIA, BELGIUM, BOSNIA AND HERZEGOVINA, BULGARIA, CROATIA, CZECH REPUBLIC, ESTONIA, FINLAND, GEORGIA, HUNGARY, ITALY, ISRAEL, KAZAKHSTAN, LITHUANIA, LATVIA, MACEDONIA, MONTENEGRO, NORWAY, OMAN, POLAND, PORTUGAL, ROMANIA, RUSSIAN FEDERATION, SAUDI ARABIA, SOUTH AFRICA, SLOVENIA, SLOVAKIA, SERBIA, SPAIN, SWEDEN, TURKEY, UNITED KINGDOM, UNITED ARAB EMIRATES, SWITEZERLAND	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report *To be adapted locally*	
Reference number assigned by the manufacturer FCA-2015-001	
FSCA reference number assigned by NCA *To be completed locally*	
Incidence reference number assigned by NCA Not Reported	
Name of the co-ordinating national competent authority (if applicable) Swissmedic (Switzerland)	
2. Information on submitter of the report	
Status of Submitters ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Other (identify the role)	
3. Manufacturer information	
Name Baxter Healthcare SA	
Contact name *To be adapted locally*	
Address Thurgauerstr. 130	
Postcode 8152	City Glattpark (Opfikon)
Phone +41.44.87.86.247	Fax +41.44.878.63.50
E-mail *To be completed locally*	Country Switzerland
4. Authorized representative information	
Name N/A	
Contact name	

Address	
Postcode	City
Phone	Fax
E-mail	Country
5. National contact point information *(to be completed locally)*	
National contact point name	
Name of the contact person	
Address	
Postcode	City
Phone	Fax
E-mail	Country
6. Medical device information	
Class ☐ AIMD Active implants ☐ MDD Class III ☐ MDD Class IIb ☒ MDD Class IIa ☐ MDD Class I	 ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code 35000
Nomenclature text : Tubing set, peritoneal dialysis	
Commercial name/brand name/make MiniCap with Povidone-Iodine	
Model number	Catalogue number BEPC4466, SPC4466
Serial number(s)	lot/batch number(s) 13J23H15, 14B23H15
Device Manufacturing date BEPC4466: 27Oct2013 SPC4466: 28Feb2014	Expiry date BEPC4466: 31Mar2015 SPC4466: 31Jul2015
Software version number (if applicable)	
Accessories/associated device (if applicable)	
Notified body (NB) ID- number TUV-0123 - TÜV Product Service GMBH	
7. Description of FSCA	
Background information and reason for the FSCA Baxter Healthcare Corporation is issuing a recall for the specific lot numbers of the MiniCAP with Povidone-Iodine Solution due to complaints received indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap or missing from the cap. Baxter is investigating the root cause of this issue.	

Description and justification of the action (corrective/preventive)

Use of MiniCaps with sponges fully separated or missing from the caps may compromise the ability of the MiniCap to provide a sterile barrier protection at the end of the tip of the transfer set, when the patient is not performing a therapy. This may increase the risk of peritonitis.
Use of MiniCaps with sponges partially protruding from the caps may encourage non-aseptic techniques, such as inadvertently touching the sponge to reposition it inside the cap. This may increase the risk of peritonitis.
Therefore as a conservative approach Baxter has decided to recall the product codes of 2 specific batches mentioned above.

Advice on actions to be taken by the distributor and the user
Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)
Baxter is asking the customers to follow the steps below:

1. Locate and remove all affected products from customer's facility.
2. Contact Baxter Healthcare Center for Service to arrange the return and credit.
3. If the product is received directly from Baxter, then complete the enclosed customer reply form and return it to Baxter.
4. If this information is received by a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, then notify their customers of this action so that they can locate and remove all affected products.

Attached please find *(to be adapted locally)*	FSN Status
☐ Field Safety Notice (FSN) in English	☐Draft
☐ FSN in national language	☒ Final
☐ Others (please specify):	

Time schedule for the implementation of the different actions

Implementation date : *(to be adapted locally)*
Regional targeted closure date : **30 Nov 2015**
Local targeted closure date : **16 Nov 2015**

These countries within the EEA and Switzerland and Turkey are affected by this FSCA
Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☐ CH	☐ CY	☒ CZ	☐ DE	☐ DK	☒ EE	☒ ES
☒ FI	☐ FR	☒ GB	☐ GR	☒ HU	☐ IE	☐ IS	☒ IT	☐ LI	☒ LT
☐ LU	☒ LV	☐ MT	☐ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI
☒ SK	☐ TR								

Candidate Countries:
☒ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
ALBANIA, BOSNIA AND HERZEGOVINA, GEORGIA, ISRAEL, KAZAKHSTAN, MACEDONIA, MONTENEGRO, OMAN, RUSSIAN FEDERATION, SAUDI ARABIA, SOUTH AFRICA, SERBIA, TURKEY, UNITED ARAB EMIRATES

8. Comments

N/A

I affirm that the information given above is correct to the best of my knowledge.

……
Signature

Name City Date

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