Field Safety Corrective Action Report Form
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative Information	
Destination Ministry of Health Vigilance on Medical Devices Via Giorgio Ribotta 5, IT - 00144 Roma Italy	
Type of Report ☐ Initial report ☐ Follow up report ☒ Final report	
Date of this Report 30 October 2015	
Reference Number Assigned by Manufacturer 21833502-01/19/2015-001-R	
FSCA Reference Number Assigned by NCA 2015/001/029/071/001	
Incidence Reference Number Assigned by NCA N/A	
Name of the Coordinating National Competent Authority (if applicable) MHRA	
2. Information on Submitter of the Report	
Status of submitter ☐ **Manufacturer** ☐ **Authorised Representative within EEA, Switzerland and Turkey** ☒ **Others: (identify the role):** Smiths Medical Risk Management Specialist on Manufacturer's Behalf	
3. Manufacturer Information	
Manufacturer Name Smiths Medical ASD, Inc.	
Manufacturer's Contact Person Tim Giguere	
Address 1265 Grey Fox Road	
Postal Code 55112	**City** St. Paul
Phone 651 628 7477	**Fax** n/a
E-mail tim.giguere@smiths-medical.com	**Country** USA
4. Authorised Representative Information	
Name of Authorised Representative Smiths Medical International Ltd.	

Authorised Representative's Contact Person Marco Savino	
Address 1500 Eureka Park, Lower Pemberton, Kent	
Postal Code TN25 4BF	**Postal Code** TN25 4BF
Phone 39 0773 4084810	**Phone** 39 0773 4084804
E-mail eu.rep@smiths-medical.com	**Country** United Kingdom
5. National Contact Point Information	
National Contact Point Name Smiths Medical International Ltd.	
Name of the Contact Person Marco Savino	
Address 1500 Eureka Park, Lower Pemberton, Kent	
Postal Code TN25 4BF	**Postal Code** TN25 4BF
Phone 39 0773 4084810	**Phone** 39 0773 4084804
E-mail eu.rep@smiths-medical.com	**Country** United Kingdom
6. Medical Device Information	
Class ☐ AIMD Active Implants ☐ MDD Class III ☐ IVD Annex II List A ☐ MDD Class IIb ☐ IVD Annex II List B ☒ MDD Class IIa ☐ IVD Devices for Self-Testing ☐ MDD Class I ☐ IVD General	
Nomenclature System (preferable GMDN) GMDN	**Nomenclature Code** 35127
Nomenclature Text Intravenous fluid container, single use	
Commercial Name/ Brand Name / Make CADD™ Medication Cassette Reservoir	
Model Number N/A	**Catalogue Number** 21-7001-24, 21-7301-24
Serial Number(s) N/A	**Lot/ Batch Number(s)** 21-7001-24, Lot Numbers 14X-297 and 14X-323. 21-7301-24, Lot Number 14X-324
Device Manufacturing Date 14X297 -- 12-June-2014	**Expiry Date** June 2019

14X323 -- 21-June-2014 14X324 -- 21-June-2014	

Software Version Number (if applicable)
N/A

Accessories/ Associated Device (if applicable)
N/A

Notified Body (NB) ID Number
0473

7. Description of FSCA

Background Information and Reason for the FSCA:

Smiths Medical has become aware of an issue with specific lots of 50mL CADD™ Medication Cassette Reservoirs ("Cassette"). Some Cassettes may leak at the sealing area of the pump tube and medication bag. Smiths Medical has received no reports of serious injury or death related to this issue.

Examination of Cassettes returned for investigation confirmed leakage at the sealing area of the pump tube and medication bag. Investigation found that the complaints with confirmed leaking were limited to 3 finished goods lots. Despite an in-depth investigation, we have not identified a definitive root cause. Bag and tube material, set-up related training and technician training were all investigated and eliminated as potential root causes. The most probable root causes found during the investigation are machine and process related:

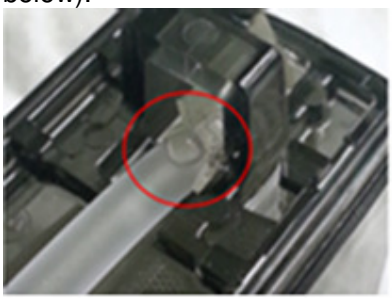
1. Damaged plate holder mandrels;

2. Failures in the grounding mechanism of the power supplied to the dies; and/ or

3. Worn motor brushes.

Description and Justification of the Action (Corrective/ Preventive):

As discussed within the Risk Analysis Summary submitted with the original notification; despite in-depth investigation, the definite root cause for the leakage was not identified. However, the root cause was isolated to manufacturing. The issue occurred during production when the pump tube and medication bag were sealed together (this "sealing area" of the product is circled in photo below).



The potential root causes were defined as:
1. Damaged plate holder mandrels (equipment related);
2. Failures in the grounding mechanism of the power supplied to the dies (equipment and process related).

In order to address these 2 potential root causes identified, Smiths Medical has implemented the following actions:

Preventive Maintenance Procedure for the bag machine was updated to include weekly inspection of the plate holder mandrels and ground strap. The ground strap is the mechanism used to supply power to the dies during the sealing operation.

The actions taken address potential root causes 1 and 2 above.

Advice on Actions to be Taken by the Distributor and the User:
All consignees were sent an Urgent Field Safety Notice via mail service to notify them of this Field Action. Consignees were instructed to return the product for credit or replacement. Distributors were instructed to notify their customers. The Urgent Field Safety Notice included a Confirmation Form that consignees were instructed to send back to Smiths Medical for carrying out the action and tracking effectiveness.

Progress of FSCA with Reconciliation Data (Mandatory for a Final FSCA)
All affected consignees in Italy have sent Smiths Medical their acknowledgement of receipt of this notice and returned affected stock. This action has been completed for Italy.

Attached Please Find	**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:
Please see above.

These Countries Within the EEA, Switzerland, and Turkey are Affected by this FSCA:

Within the 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:
AE, AU, CA, CO, ID, SG, US, ZA

8. Comments:
As Smiths Medical's Notified Body, Intertek, is located in the UK, Smiths Medical recognizes the MHRA as the Lead Competent Authority for this product.

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

Ellen Riebe
Signature

30 October 2015
Date

Ellen Riebe
Name

St. Paul, MN
City

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.