import XML | fix + save

fill with test data #1

new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?
San Marino

Type of report
- ○ Initial report
- ○ Follow-up report
- ◉ Final report

Date of this report
2025-07-03

Reference number assigned by the manufacturer
BDB-25-5314

FSCA reference number assigned by NCA
Not known

Incidence reference number assigned by NCA

Name of the co-ordinating NCACompetent Authority (if applicable)
HPRA

2 Information on submitter of the report

Status of submitter
- ○ Manufacturer
- ○ Authorised Representative within EEA and Switzerland
- ◉ Others: (identify the role) Field Action Coordinator

3 Manufacturer information | new

Name
Becton, Dickinson and Company

Contact Name
Mirna Dipano

Address
155 North McCarthy Boulevard, California

Postcode	**City**
95035	Milpitas
Phone	**Fax**
0	
E-mail	**Country**
EMEAFieldAction@bd.com	US - USA

4 Authorised Representative Information	new

Name Becton Dickinson Ireland Ltd.	
Contact Name Larissa Pinon Ferreira	
Address Donore Road, Drogheda	
Postcode A92 YW26	**City** Co. Louth,
Phone 0	**Fax**
E-mail EMEAFieldAction@bd.com	**Country** IE - Ireland

5 National contact point information	new

National contact point name Becton Dickinson	
Name of the contact person Lorna Darrock	
Address 1030 Eskdale Road, Winnersh Triangle	
Postcode RG41 5TS	**City** Wokingham
Phone +44 7769 640757	**Fax**
E-mail EMEAFieldAction@bd.com	**Country** GB - Great Britain

6 Medical device information | new

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)	**Nomenclature code**
GMDN	58048

Nomenclature text
Optical instrument performance standard calibrator

Commercial name/ brand name / make
BD FACS™ 7-Color Setup Beads

Model number	**Catalogue number**
	see FSN
Serial number(s)	**Lot/batch number(s)**
	see FSN
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number
N/A

Accessories / associated devices (if applicable)

Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

Based on customer feedback, BD has identified errors in the spectral overlap factors (SOF) table provided for specific lots of BD FACS™ 7-Color Setup Beads as listed in the FSN.

This issue may affect the accuracy of flow cytometry data due to incorrect flow cytometry setup compensation values for multicolor reagents for which proper fluorescence compensation is required prior to analyzing samples.

Description and justification of the action (corrective / preventive)

BD is issuing a Field Safety Corrective Action (Advisory) for specific lot numbers of BD FACS™ 7-Color Setup Beads as listed in the FSN.

The impacted lots of the BD FACS™ 7-Color Setup Beads have the potential to create a hazardous situation that compromises the accurate setup of the flow cytometry instrument prior to analyzing samples using multicolor reagents, which can lead to potential erroneous results, may delay results and might impact health care management decisions. This may also result in the subject having to return for additional sample collection.

Advice on actions to be taken by the distributor and the user

Refer to the FSN

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

In the San Marino market, BD has achieved a 100% response rate to the Advisory Notice (1 customer from 1 customer responded).

This is Field Action is now closed.

Time schedule for the implementation of the different actions

NA

Attached please find

- [x] Field Safety Notice (FSN) in English
- [x] FSN in national language
- [ ] Others (please specify)

FSN Status

- ( ) Draft FSN
- (•) Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

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

Candidate Countries

- [ ] HR

- [ ] All EEA, candidate countries and Switzerland

Others:

8 Comments

Classification: IVDR, Class A

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

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

print | check | send XML-data by E-Mail