



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**  
No. **2021-3528**

14 DEC 2021

**TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT: Voluntary Recall of Smartsite Needle-Free Valve and BD Gravity (Vented DEHP-Free Set with Anti-Run Dry and Auto Prime and Needle Free Valve)**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Smartsite Needle-Free Valve and BD Gravity (Vented DEHP-Free Set with Anti-Run Dry and Auto Prime and Needle Free Valve) with FDA registration number, MDR-04705, MDR-05907 and MDR-06272, imported and distributed by KSM Healthcare, Inc.:

| Product Description         | Item Code # | Expiry Date | Lot/Batch # | Quantity |
|-----------------------------|-------------|-------------|-------------|----------|
| Smartsite Needle-Free Valve | 388002      | 30/04/2021  | 1008404     | 10600    |
| Smartsite Needle-Free Valve | 388002      | 31/05/2021  | 1008870     | 10800    |
| Smartsite Needle-Free Valve | 388002      | 30/06/2021  | 1009237     | 13400    |
| Smartsite Needle-Free Valve | 388002      | 30/06/2021  | 1009434     | 5100     |
| Smartsite Needle-Free Valve | 388002      | 30/06/2021  | 1009440     | 7500     |
| Smartsite Needle-Free Valve | 388002      | 31/07/2021  | 1009518     | 8000     |
| Smartsite Needle-Free Valve | 388002      | 31/07/2021  | 1009630     | 8700     |
| Smartsite Needle-Free Valve | 388002      | 31/08/2021  | 1009711     | 3400     |
| Smartsite Needle-Free Valve | 388002      | 31/08/2021  | 1009811     | 3000     |
| Smartsite Needle-Free Valve | 388002      | 31/08/2021  | 1009831     | 4800     |
| Smartsite Needle-Free Valve | 388002      | 31/01/2022  | 1011775     | 19500    |



|   |             |            |         |       |
|---|-------------|------------|---------|-------|
| Smartsite Needle-Free Valve                       | 388002      | 31/12/2022 | 1015690 | 11500 |
| Smartsite Needle-Free Valve                       | 388002      | 31/03/2023 | 1016658 | 22900 |
| Smartsite Needle-Free Valve                       | 388002      | 31/03/2023 | 1016760 | 23000 |
| Smartsite Needle-Free Valve                       | 388002      | 31/03/2023 | 1017102 | 13600 |
| Smartsite Needle-Free Valve                       | 388002      | 31/03/2023 | 1017103 | 18900 |
| Smartsite Needle-Free Valve                       | 388002      | 31/03/2023 | 1017104 | 18800 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017171 | 18700 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017172 | 17800 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017408 | 19200 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017409 | 3500  |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017410 | 18800 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017411 | 18500 |
| Smartsite Needle-Free Valve                       | 388002      | 30/04/2023 | 1017495 | 5400  |
|   |             |            |         |       |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 7/31/2021  | 1009589 | 14000 |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 7/31/2021  | 1009592 | 9200  |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 10/31/2021 | 1010921 | 11500 |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 11/30/2021 | 1011354 | 28000 |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 12/31/2021 | 1011677 | 14200 |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 1/31/2022  | 1011971 | 29000 |
| BD Gravity Vented DEHP-Free Set with Anti-Run Dry | 2000E7<br>D | 2/28/2022  | 1012299 | 16800 |

|   |                       |            |         |       |
|---|-----------------------|------------|---------|-------|
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 3/31/2022  | 1012480 | 7600  |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 4/30/2022  | 1012805 | 16700 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 6/30/2022  | 1013422 | 30400 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 6/30/2022  | 1013423 | 600   |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 6/30/2022  | 1013567 | 17800 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 6/30/2022  | 1013663 | 10600 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 7/31/2022  | 1013835 | 21800 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 8/31/2022  | 1014031 | 7900  |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 8/31/2022  | 1014139 | 15100 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 9/30/2022  | 1014264 | 14300 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 9/30/2022  | 1014321 | 12200 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 9/30/2022  | 1015163 | 55100 |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 11/30/2022 | 1015404 | 5800  |
| BD Gravity Vented<br>DEHP-Free Set with<br>Anti-Run Dry | 2000E7<br>D           | 11/30/2022 | 1015502 | 3800  |
|   |                       |            |         |       |
| Auto Prime and<br>Needle Free Valve                     | 041000<br>06162-<br>A | 4/30/2021  | 543653  | 9750  |
| Auto Prime and<br>Needle Free Valve                     | 041000<br>06162-<br>A | 7/31/2021  | 545737  | 750   |

|                                  |                   |            |        |       |
|----------------------------------|-------------------|------------|--------|-------|
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 12/31/2022 | 555334 | 750   |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 1/31/2023  | 555935 | 750   |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 3/31/2023  | 557207 | 750   |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 7/31/2021  | 547481 | 5000  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 8/31/2021  | 547961 | 10800 |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 10/31/2021 | 548800 | 9200  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 10/31/2021 | 549178 | 8000  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 12/31/2021 | 549181 | 6400  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 12/31/2021 | 550268 | 2600  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 12/31/2021 | 550630 | 1200  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 2/28/2022  | 551263 | 10800 |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 3/31/2022  | 551391 | 11600 |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 4/30/2022  | 551392 | 1000  |
| Auto Prime and Needle Free Valve | 041000<br>06162-A | 4/30/2022  | 547481 | 7600  |
| Auto Prime and Needle Free Valve | 041000<br>06162A  | 4/30/2022  | 547961 | 13200 |

Figure 1. SmartSite Needle Free Valve



FRONT



BACK

FRONT



BACK

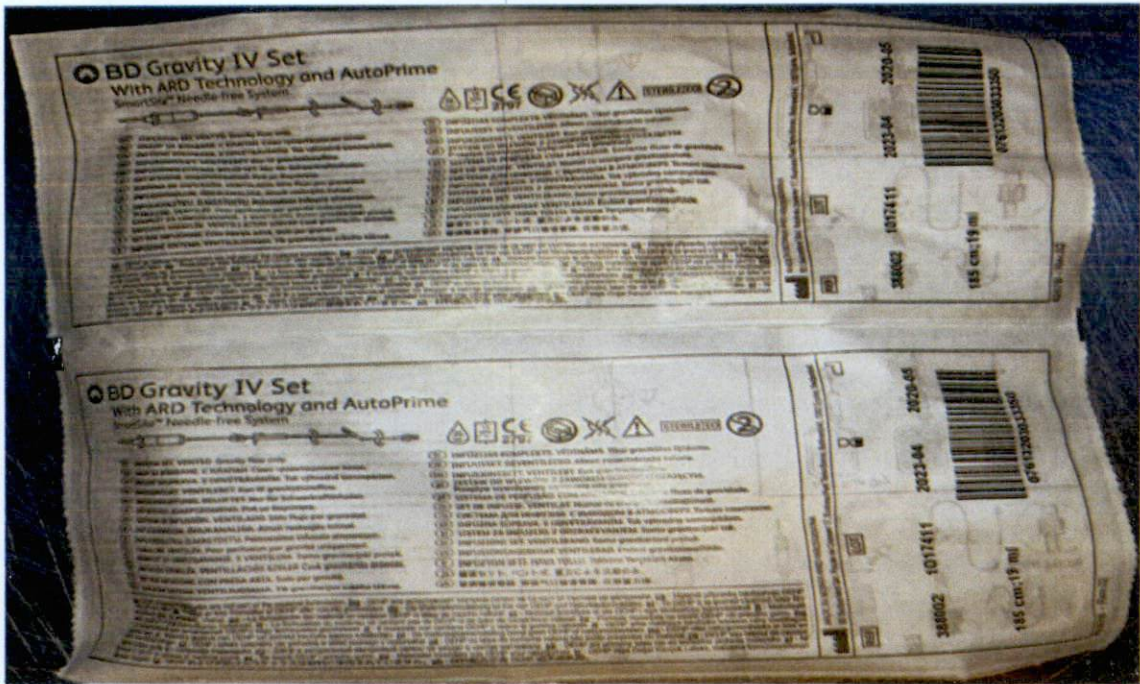


Figure 2. BD Gravity IV Set with ARD Technology AutoPrime

FRONT



BACK

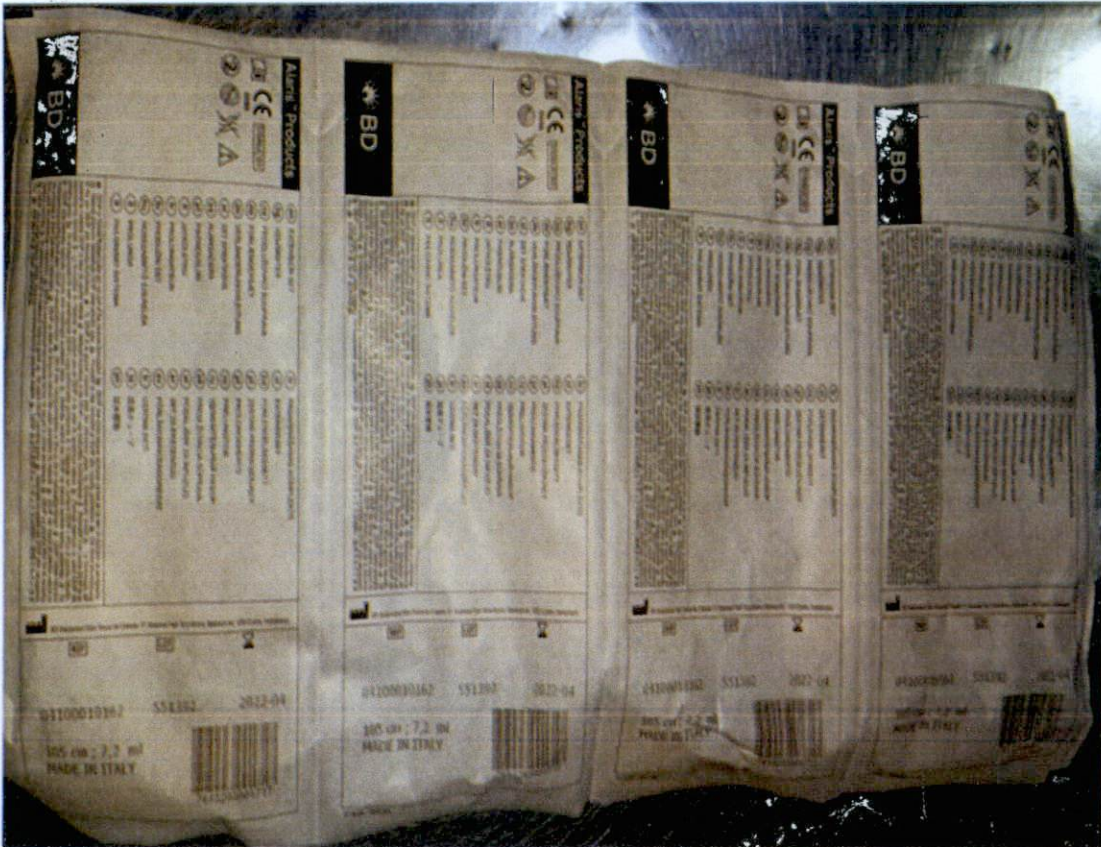


Figure 3. Auto Prime and Needle Free Valve

BD Holdings Singapore Pte. Ltd., informed KSM Healthcare, Inc. that they are voluntarily recalling the above-mentioned specific lots/batches of Smartsite Needle-Free Valve and BD Gravity (Vented DEHP-Free Set with Anti-Run Dry and Auto Prime and Needle Free Valve). BD has been notified by a 3rd party sterilization services provider that it intentionally falsified sterilization process records related to the processing of BD products.

BD has not identified any reports of adverse events or serious patient harm to date that could be associated with this Voluntary Product Recall. No specific patient follow up activities are required if the product has already been used.

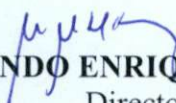
In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Smartsite Needle-Free Valve and BD Gravity (Vented DEHP-Free Set with Anti-Run Dry and Auto Prime and Needle Free Valve).

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at [cdrhr@fda.gov.ph](mailto:cdrhr@fda.gov.ph), or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

DTN 20210326192622