



**MEDICAL DEVICE RECALL LISTING SEPTEMBER 2022**

| <b>Date Received</b>    | <b>Reference No.</b>           | <b>Recall Type</b> | <b>Product Name</b>                                 | <b>Product Registration</b> | <b>Recall Class</b> | <b>Reason of Recall</b>                                     | <b>Recalling Establishment</b>          | <b>Establishment License</b> |
|-------------------------|--------------------------------|--------------------|---|-----------------------------|---------------------|---|---|------------------------------|
| <b>1 September 2022</b> | MDA/Recall/P0050-96747583-2022 | Voluntary recall   | TELEFLEX GIBECK ISO-GARD FILTER WITH CATHETER MOUNT | GB19922768318               | Class II            | A23: Use of Device Problem                                  | TELEFLEX MEDICAL SDN.BHD                | MDA-3059-K121                |
| <b>1 September 2022</b> | MDA/Recall/P0053-35044341-2022 | Voluntary recall   | PREVAIL PACLITAXEL-COATED PTCA BALLOON CATHETER     | GD9712721-75150             | Class II            | A21: Labelling, Instructions for Use or Training Problem    | MEDTRONIC MALAYSIA SDN BHD              | MDA-0074-WDP7414             |
| <b>5 September 2022</b> | MDA/Recall/P0054-89062176-2022 | Voluntary recall   | VERITAS VISION SYSTEM                               | GC2538221-71446             | Class III           | A24: Adverse Event Without Identified Device or Use Problem | JOHNSON & JOHNSON SDN BHD.              | MDA-0081-WDP415              |
| <b>5 September 2022</b> | MDA/Recall/P0055-75032065-2022 | Voluntary recall   | HD-BLOODLINES AV-SETS                               | GB110721062918              | Class III           | A02: Manufacturing, Packaging or Shipping Problem           | FRESENIUS MEDICAL CARE MALAYSIA SDN BHD | MDA-1215-WDP120              |

\* The information contained in the Medical Device Authority Recall database is released under Regulation 7(8) and Regulation 8 (5) of Malaysia's Medical Device Regulations 2019.