MEDICAL DEVICE RECALL LISTING AUGUST 2023

Date Received	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
01/08/2023	MDA/Recall/P0191-38483717-2023	Voluntary Recall	STRYKER MIXEVAC3 BONE CEMENT MIXER	GC12682730018	Class II	A02: Manufacturing, Packaging or Shipping Problem	STRYKER CORPORATION (MALAYSIA) SDN. BHD.	MDA-2123-WDP121
02/08/2023	MDA/Recall/P0195-80159537-2023	Voluntary Recall	VENTANA ANTI-ALK (D5F3) RABBIT MONOCLONAL PRIMARY ANTIBODY	IVDC45906209918	Class III	A02: Manufacturing, Packaging or Shipping Problem	ROCHE DIAGNOSTICS (M) SDN. BHD.	MDA-1674-WDP121
04/08/2023	MDA/Recall/P0194-80425453-2023	Voluntary Recall	PDS™ II (POLYDIOXANONE) STERILE SYNTHETIC, ABSORBABLE SUTURE	GD4349722-103519	Class III	A02: Manufacturing, Packaging or Shipping Problem	JOHNSON & JOHNSON SDN BHD	MDA-4880-WDP123
04/08/2023	MDA/Recall/P0196-10265681-2023	Voluntary Recall	PDS PLUS ANTIBACTERIAL (POLYDIOXANONE) SUTURE	GD10453922-102675	Class III	A02: Manufacturing, Packaging or Shipping Problem	JOHNSON & JOHNSON SDN BHD	MDA-4880-WDP123
28/08/2023	MDA/Recall/P0204-86872369-2023	Voluntary Recall	3M ATTEST SUPER RAPID READOUT BIOLOGICAL INDICATOR 1492V	GMD34608856218A	Class III	A23: Use of Device Problem	3M MALAYSIA SDN BHD	MDA-2255-WP121
29/08/2023	MDA/Recall/P0198-40556954-2023	Voluntary Recall	IMMUNOHAEMATOLOGY BLOOD GROUPING ANTISERA	IVDD52033101418	Class III	A27: Appropriate Term/Code Not Available	UNITED ITALIAN TRADING (M) SDN. BHD	MDA-1847-WDP121

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29/08/2023	MDA/Recall/P0205-45964073-2023	Voluntary Recall	BIO-AQUACEL EYE SAFE	GB9985320-46507	Class II	A18: Contamination / decontamination Problem	FARMASIA SDN BHD	MDA-1705-W121

* 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.