

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	02/01/2026	Olympus to Emphasizes Compliance to the IFU and System Manual & To Provide Additional Instructions	RESECTOSCOPE SYSTEM	MDA/FCA/P1556-38865552-2026	GC75601857218	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
2	02/01/2026	Olympus to Repair the Miswiring	SHOCKPULSE-SE LITHOTRIpsy SYSTEM	MDA/FCA/P1557-71420701-2026	GC92154340917	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
3	07/01/2026	Zimmer Air Dermatomes - Dermatome Thickness Control Bar Misalignment	ZIMMER AIR DERMATOMES	MDA/FCA/P1570-87518338-2026	GB96045673518	ZIMMER MEDICAL (MALAYSIA) SDN BHD sarah.mohdyunos@zimmerbiomet.com
4	07/01/2026	SPRINTER CART (XL) – Missing ‘Pushing prohibited’ label	ROTAFLOW II SYSTEM	MDA/FCA/P1575-87464528-2026	GC7519323-144960	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
5	27/01/2026	AEROSOL MASK (ADULT) WITH CONNECTING TUBE 2.5M, LESS AND SLOW MIST OUTPUT.	AEROSOL MASK WITH CONNECTING TUBE	MDA/FCA/PX1577-35764843-2026	GB9722022-110907	MYMEDIC INNOVATION SDN BHD farkhan@mymedic.com.my
6	29/01/2026	AEROSOL MASK (ADULT) WITH CONNECTING TUBE 2.5M, NO MIST OUTPUT.	AEROSOL MASK WITH CONNECTING TUBE	MDA/FCA/PX1581-10026626-2026	GB9722022-110907	MYMEDIC INNOVATION SDN BHD farkhan@mymedic.com.my
7	29/01/2026	AEROSOL MASK (ADULT) WITH CONNECTING TUBE 2.5M, LESS AND SLOW MIST OUTPUT.	AEROSOL MASK WITH CONNECTING TUBE	MDA/FCA/PX1580-46378665-2026	GB9722022-110907	MYMEDIC INNOVATION SDN BHD farkhan@mymedic.com.my
8	13/01/2026	To advise the details of the shelf life discrepancy and what actions to be taken, should device labelling indicate the discrepancy - Gelweave	GELWEAVE VASCULAR PROSTHESIS	MDA/FCA/P1584-20930336-2026	GD94369461417	TERUMO MALAYSIA SDN. BHD. TMSB_RAQ@terumo.co.jp
9	13/01/2026	To advise the details of the shelf life discrepancy and what actions to be taken, should device	GELSOFT PLUS VASCULAR PROSTHESIS	MDA/FCA/P1585-60604142-2026	GD43852800518	TERUMO MALAYSIA SDN. BHD. TMSB_RAQ@terumo.co.jp

		labelling indicate the discrepancy - Gelsoft Plus				
10	14/01/2026	Cybersecurity vulnerability affecting Centricity RIS-i configured with Instant Messenger	Centricity RIS-i	MDA/FCA/P1589-54679144-2026	GA1620121-61938	GE HEALTHCARE SDN. BHD premarket.my@ge.com
11	28/01/2026	2024-IGT-BST-020 - Philips Azurion systems unexpected table movement	AZURION 3	MDA/FCA/P1624-80058829-2026	GC99381544218	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
12	28/01/2026	2024-IGT-BST-020 - Philips Azurion systems unexpected table movement	AZURION 5	MDA/FCA/P1630-65804144-2026	GC10785320-48186	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
13	28/01/2026	2024-IGT-BST-020 - Philips Azurion systems unexpected table movement	AZURION 7	MDA/FCA/P1631-50276960-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
14	28/01/2026	2024-IGT-BST-020 - Philips Azurion systems unexpected table movement	AZURION BIPLANE	MDA/FCA/P1632-66510304-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com

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