

ENDORSED DRUG-MEDICAL DEVICE PRODUCTS 2023

NO.	APPLICANT DETAILS	DEVICE NAME	PRODUCT NAME	NAME AND ADDRESS OF DEVICE MANUFACTURER	EL REFERENCE NUMBER	EL RELEASE DATE
1	Pfizer (Malaysia) Sdn. Bhd. Level 10&11 Wisma Averis Tower 2, Avenue 5 Bangsar South No.8 Jalan Kerinchi 59200 Kuala Lumpur.	Pre-filled Syringe	Nivestim Solution for Injection/Infusion 120mcg/0.2ml & 300mcg/0.5ml (MAL13085064ARZ & MAL13085067ARZ)	Becton, Dickinson and Company, 11. rue Aristide Berges- ZI des Iles, 38800 Le Pont de Claix, France.	(2) dlm.MDA 600-1/6/22 JLD 31	10/13/2023
2	Pfizer (Malaysia) Sdn. Bhd. Level 10&11 Wisma Averis Tower 2, Avenue 5 Bangsar South No.8 Jalan Kerinchi 59200 Kuala Lumpur.	Pre-Filled Pen	1- Genotropin® 5.3mg Powder and Solvent for Solution for Injection (MAL20081840AZ) 2- Genotropin® 12mg Powder and Solvent for Solution for Injection (MAL20081841AZ)	Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs, Belgium.	(2) dlm.MDA 600-1/6/22 JLD 27	8/8/2023
3	Zuellig Pharma Sdn. Bhd. No. 15 Persiaran Pasak Bumi Section U8, Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor Darul Ehsan.	Injection kits (Syringe and Needles)	Diphereline P.R. Powder and Solvent for Suspension for Injection 11.25 mg/vial	STERISERVICES 20 rue des Canadiens, 27300 Bernay, France.	(6) dlm.MDA 600-1/6/22 JLD 24	7/7/2023
4	Novartis Corporation (Malaysia) Sdn. Bhd. Level 18, Imazium, No.8 Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor	PFS & Needle SafetyGlide 21G x 1 1/2 in Needle	Fulvestrant Sandoz Solution for Injection in Pre-filled Syringe 250mg/5ml	Becton, Dickinson and Company BD Medical Delivery Solutions Franklin Lakes, New Jersey 07417.	(6) dlm.MDA 600-1/6/22 JLD 23	6/9/2023
5	Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18, Tower B, Plaza 33, No 1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.	Pre-filled Pen	1- Soliqua SoloStar 100units/mL+33mcg/mL Solution for Injection in a Pre-filled pen (MAL19056043AZ) 2- Soliqua SoloStar 100units/mL+50mcg/mL Solution for Injection in a Pre-filled pen (MAL19056044AZ)	-	(6) dlm.MDA 600-1/6/22 JLD 29	7/6/2023
6	IDB Resources Sdn. Bhd. A-10-01 Tropicana Avenue, Persiaran Tropicana, 47410 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	BESREMi 500mcg/mL Solution for Injection in Pre-filled Syringe	Becton Dickinson (BD) 11, rue Aristide Berges, BP4, LE PONT DE, CLAX CEDEX, 38801, France.	(4) dlm.MDA 600-1/6/22 JLD 34	8/28/2023

7	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Needle	Engerix-B 10 Junior Dose Suspension for Injection (MAL19880327ARZ)	Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuven, Belgium.	(4) dlm.MDA 600-1/6/22 JLD 71	25/11/2024
8	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Needle	Engerix-B 20 Adult Dose Suspension for Injection (MAL19871425ARZ)	Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuven, Belgium.	(4) dlm.MDA 600-1/6/22 JLD 72	??
9	Amgen Biopharmaceuticals Malaysia Sdn. Bhd. Suite 9.01, Level 9, Menara Summit Persiaran Kewajipan USJ 1, UEP 47600 Subang Jaya, Selangor.	Pre-filled Syringe and Needle	Amgevita 20mg/0.4ml Solution for Injection in Pre-filled Syringe	Amgen Manufacturing Limited, State Road 31, Kilometer 24.6, Juncos, Puerto Riso 00777, USA.	4) dlm.MDA 600-1/6/22 JLD 30	7/31/2023
10	Bayer Co. (M) Sdn. Bhd. 25-03 & 25-04, Level 25, Imazium No.8 Jalan SS21/37, Damansara Uptown 47400 Petaling Jaya.	Levonorgestrel Intrauterine Delivery System 52mg with Inserter (MIRENA)	Mirena Intrauterine System 20mcg/24hours	Bayer Oy Pansiontie 47, 20210 Finland.	(2) dlm.MDA 600-1/6/22 JLD 34	11/16/2023
11	First Pharmaceutical Sdn. Bhd. No.20 Jalan SS 19/5, 47500 Subang Jaya Selangor.	Pre-filled Syringe	Aguettant Ephedrine 3mg/ml, Solution for Injection in Pre-filled Syringe	Laboratoire Aguettant Lieu-dit Chantecaille, 07340 Champagne, France.	(2) dlm.MDA 600-1/6/22 JLD 24	5/17/2023
12	Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18, Tower B, Plaza 33, No 1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.	Pre-filled Syringe	FluQuadri Quadrivalent Influenza Vaccine 0.5ml (MAL14075039ARZ)	-	(2) dlm.MDA 600-1/6/22 JLD 32	8/8/2023
13	Fresenius Medical Care Malaysia Sdn. Bhd. Second Floor, Axis Technology Centre Lot 13, Jalan 51A/225, 46100 Petaling Jaya, Selangor.	Drainage Bag, Transfer System, and System Connector	1- CAPD/DPCA 17 Stay Safe Peritoneal Dialysis Solution 2- CAPD/DPCA 18 Stay Safe Peritoneal Dialysis Solution 3- CAPD/DPCA 19 Stay Safe Peritoneal Dialysis Solution 4- CAPD/DPCA 2 Stay-Safe Peritoneal Dialysis Solution 5- CAPD/DPCA 4 Stay-Safe Peritoneal Dialysis Solution	Fresenius Medical Care Deutschland GmbH Frankfurter Strabe 6-8, 66606 St. Wendel, Germany	(4) dlm.MDA 600-1/6/22 JLD 24	6/9/2023

14	Fresenius Medical Care malaysia Sdn. Bhd. Second Floor, Axis Technology Centre Lot 13, Jalan 51A/225, 46100 Petaling Jaya, Selangor.	Connective Tubing, Injection Unit, Transfer System, and Sleep Safe Connector	1- CAPD/DPCA 17 Sleep Safe Peritoneal Dialysis Solution 2- CAPD/DPCA 18 Sleep Safe Peritoneal Dialysis Solution 3- CAPD/DPCA 19 Sleep Safe Peritoneal Dialysis Solution	Fresenius Medical Care Deutschland GmbH Frankfurter Strabe 6-8, 66606 St. Wendel, Germany	(2) dlm.MDA 600-1/6/22 JLD 41	12/12/2023
15	Fresenius Medical Care malaysia Sdn. Bhd. Second Floor, Axis Technology Centre Lot 13, Jalan 51A/225, 46100 Petaling Jaya, Selangor.	Drainage Bag, Transfer System, and System Connector	1- Stay Safe Balance 1.5% glucose 1.25mmol/L calcium peritoneal dialysis solution bag, 2-Stay Safe Balance 1.5% glucose 1.75mmol/L calcium peritoneal dialysis solution bag, 3- Stay Safe balance 2.3% glucose 1.25mmol/L calcium peritoneal dialysis solution bag, 4- Stay Safe Balance 2.3% glucose 1.75mmol/L calcium peritoneal dialysis solution bag, 5- Stay Safe Balance 4.25% glucose 1.25mmol/L calcium peritoneal dialysis solution bag, 6- Stay Safe Balance 4.25% glucose 1.75mmol/L calcium peritoneal dialysis solution bag	Fresenius Medical Care Deutschland GmbH Frankfurter Strabe 6-8, 66606 St. Wendel, Germany	(2) dlm.MDA 600-1/6/22 JLD 40	11/28/2023
16	DCH Auriga (Malaysia) Sdn. Bhd. Lot 6, Persiaran Perusahaan Seksyen 23, 40300 Shah Alam Selsngor.	Pre-filled Syringe and Needle	1- Eligard 7.5mg Powder & Solvent for Solution for Injection 2- Eligard 22.5mg Powder & Solvent for Solution for Injection 3- Eligard 45mg Powder & Solvent for Solution for Injection	1- Tolmar Inc. 701 Centre Avenue, Ft. Collins, 80526, United States. 2- Terumo (Philippines) Corporation 124 East Main Avenue, Laguna Technopark, Binan, Laguna, 4024, Philippines.	(4) dlm.MDA 600-1/6/22 JLD 39	12/4/2023
17	PharmEng Technology Sdn. Bhd. 1 Sentral, Level 16, Jalan Stesen Sentral 5, KL Sentral, 50470 Kuala Lumpur.	Collagen Sponge	Tachosil Medicated Sponge	Takeda Austria GmbH St. Peter Strasse 25, 4020 Linz, Austria	(2) dlm.MDA 600-1/6/22 JLD 57	3/7/2024
18	Bayer Co. (M) Sdn. Bhd. 25-03 & 25-04, Level 25, Imazium No.8 Jalan SS21/37, Damansara Uptown 47400 Petaling Jaya.	Pre-filled Syringe	Gadovist 1.0mmol/ml solution for injection pre-filled syringe	Becton Dickinson France S.A.S Pharmaceutical Systems 11 rue Aristide Berges, Le Pont-de-Claix, 38800, France	(4) dlm.MDA 600-1/6/22 JLD 76	20/12/2024
19	Baxter Healthcare (Malaysia) Sdn. Bhd. B-21-3A, Level 21, The Ascent, Paradigm No.1, Jalan SS/7/26A Kelana Jaya 47301 Petaling Jaya, Selangor.	Drainbag Set Subassembly	1- Baxter Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose 2- Baxter Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose 3- Baxter Dianeal PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose 4- Baxter Dianeal Low Calcium (2.5 mEq/l)	Baxter Healthcare S.A Singapore Branch 2 Woodlands Industrial Park D, Street 2, 737787, Singapore.	(4) dlm.MDA 600-1/6/22 JLD 31	9/13/2023

			Peritoneal Dialysis Solution with 1.5% Dextrose 5- Baxter Dianeal Low Calcium (2.5 mEq/l) Peritoneal Dialysis Solution with 2.5% Dextrose 6- Baxter Dianeal Low Calcium (2.5 mEq/l) Peritoneal Dialysis Solution with 4.25% Dextrose 7- Baxter Dianeal Low Calcium (2.5 mEq/l) Peritoneal Dialysis Solution with 1.5% Dextrose 8- Baxter Dianeal Low Calcium (2.5 mEq/l) Peritoneal Dialysis Solution with 2.5% Dextrose			
20	Pfizer (Malaysia) Sdn. Bhd. Level 10&11 Wisma Averis Tower 2, Avenue 5 Bangsar South No.8 Jalan Kerinchi 59200 Kuala Lumpur.	Pre-filled Syringe and Infusion Set	1- BeneFIX, powder and solvent for solution for injection 250 IU/vial (MAL20091920ACZ) 2- BeneFIX, powder and solvent for solution for injection 500 IU/vial (MAL20091921ACZ) 3- BeneFIX, powder and solvent for solution for injection 1000 IU/vial (MAL20091922ACZ) 4- BeneFIX, powder and solvent for solution for injection 2000 IU/vial (MAL20091923ACZ)	Vetter Pharma-Fertigung Schutzenstr. 87 und 99-101, 88212 Ravensburg, Germany	(4) dlm.MDA 600-1/6/22 JLD 54	9/5/2024
21	Kotra Pharma (M) Sdn. Bhd. No.1, 2 & 3 Jalan TTC 12, Cheng Industrial Estate 75250 Melaka.	Pre-filled Syringe	Vaxcel Phenylephrine 500mcg/5ml Injection Prefilled Syringe	SHANDONG WEGO PREFILLS PHARMACEUTICAL PACKAGING CO., LTD. Gate 3 and South of Gate 5 Weigao Industrial Park, No. 20 Xingshan Road Torch High-tech Industrial Development Zone 264210 Weihai, Shandong Province, People's Republic of China.	(4) dlm.MDA 600-1/6/22 JLD 61	26/9/2024
22	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	TWINRIX VACCINE (MAL19987959ARZ)	1- Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuben, Belgium 2- Becton Dickinson de Mexico S.A. de C.V, K.M. 37.5 Autopista Mexico - Queretaro, 54740 Cuautitlan, Izcalli, Estado de Mexico, Mexico	(2) dlm.MDA 600-1/6/22 JLD 68	23/10/2024
23	Camber Laboratories Sdn. Bhd. Unit D23A-3A, Level 23A, Menara Suezcap 1, No.2, Jalan Kerinchi, Gerbang Kerinchi Lestari, 59200 Kuala Lumpur.	Pre-filled Syringe and Needle	HEFULA (Fulvestrant Solution for Injection 250mg/5ml)	BD Medical Pharmaceutical System 11, rue Aristide Berges, B. P. 4, F-38801 Le Pont de Claix, France.	(4) dlm.MDA 600-1/6/22 JLD 60	19/9/2024
24	Novo Nordisk Pharma (Malaysia) Sdn. Bhd.	Pen-injector	Sogroya - Pen Injector for Somapacitan (PDS290 Pen-injector)	Novo Nordisk AS Novo Alle, DK-2880 Bagsværd, Denmark.	(4) dlm.MDA 600-1/6/22 JLD 47	2/28/2024

	Menara 1 Sentrum, Level 16 No. 201, Jalan Tun Sambanthan 50470 Kuala Lumpur.					
25	Novo Nordisk Pharma (Malaysia) Sdn. Bhd. Menara 1 Sentrum, Level 16 No. 201, Jalan Tun Sambanthan 50470 Kuala Lumpur.	Pre-filled Pen	Norditropin® NordiFlex®	Novo Nordisk AS Novo Alle, DK-2880 Bagsværd, Denmark.	(2) dlm.MDA 600-1/6/22 JLD 45	2/9/2024
26	DKSH MALAYSIA SDN. BHD. B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.	Pre-filled Syringe	BONVIVA 3MG/3ML SOLUTION FOR IV INJECTION (5mL syringe)	Gerresheimer Bünde GmbH Erich-Martens-Str, 26-32, 32257 Bünde, Germany	(2) dlm.MDA 600-1/6/22 JLD 47	2/28/2024
27	Novartis Corporation (Malaysia) Sdn. Bhd. Level 18, Imazium, No.8 Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.	Pre-filled Syringe	Pasurta 70mg/mL and 140mg/mL Solution for Injection in a Prefilled Syringe (BD HYPAK syringe)	Alcon-Couvreur NV Rijksweg 14, Puurs, 2870, Belgium.	(4) dlm.MDA 600-1/6/22 JLD 40	1/18/2024
28	Merck Sdn. Bhd. Level 3, Menara Sunway Annexe, Jalan Lagoon Timur, Bandar Sunway, 46150 Petaling Jaya, Selangor.	Pen-injector	Rebif® Solution for Injection	Becton Dickinson Faraday Road, Dorcan, Swindon, SN3 5JH, United Kingdom	(4) dlm.MDA 600-1/6/22 JLD 43	2/6/2024
29	Peritone Health Sdn. Bhd. Lot 12, Industrial Zone Phase 4, Kulim Hitech Park, 09000 Kulim, Kedah.	CAPD / APD	Peritoneal Dialysis Closure System for: 1- Soft Flow SC Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose 2.5% W/V (MAL18116040AZ) 2- Soft Flow SC Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose 1.5% W/V (MAL18116041AZ) 3- Soft Flow SC Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with Dextrose 4.25% W/V (MAL18116042AZ)	Peritone Health Sdn. Bhd. Lot 12, Industrial Zone Phase 4, Kulim Hitech Park, 09000 KULIM, Kedah.	(2) dlm.MDA 600-1/6/22 JLD 39	10/20/2023
30	AstraZeneca Sdn. Bhd. Level 11 & 12, The Bousteader, No.10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe with needle	Fasenra 30 Mg Solution For Injection in Pre-Filled Syringe	1- AstraZeneca Gärtunavägen, Södertälje, Sweden. 2- Catalent Indiana, LLC 1300 South Patterson Drive, Bloomington, Indiana 47403, USA. 3- Amylin Ohio LLC 8814 Trade Port	(4) dlm.MDA 600-1/6/22 JLD 45	13/3/2024

				Drive, West Chester, Ohio 45071, USA.		
31	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe with needle	Boostrix Vaccine (EFFIVAX SCF 1.25 mL PRTCF30 EBPP, K-Pack II Needle and Neolus Needle)	1- Becton Dickinson de México S.A de C.V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cauatilan, Izcalli, Estado de México C.P.54730, Mexico. 2- TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, Belgium.	(4) dlm.MDA 600-1/6/22 JLD 68	23/10/2024
32	Pfizer(Malaysia) Sdn. Bhd. Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No. 8, Jalan Kerinchi, 59200 Kuala Lumpur.	Pre-filled Syringe	Abrysvo Powder and Solvent for Solution for Injection	1- SCHOTT Achweiz AG St. Josefen-Straße 20, 9001 St. Gallen Postaut, Switzerland. 2- Becton Dickinson Hungary Kft. Uvegyar Ut 3 H-2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 61	19/9/2024
33	Kyowa Kirin Malaysia Sdn. Bhd. Suite A501, 5th Floor, West Wing, Wisma Consplant 2, No. 7, Jalan SS 16/1, 47500 Subang Jaya, Selangor Darul Ehsan.	Pre-filled Syringe VIII	NESP INJECTION PLASTIC SYRINGE (10mcg/0.5mL, 20mcg/0.5mL, 30mcg/0.5mL, 40mcg/0.5mL, 60mcg/0.5mL, 120mcg/0.5mL and 180mcg/0.5mL)	Terumo Corporation Kofu Factory 1727-1, Tsuiji Arai, Showa- cho, Nakakoma-gun, Yamanashi, 409-3853, Japan.	(2) dlm.MDA 600-1/6/22 JLD 52	15/4/2024
34	Dr. Reddy's Laboratories Malaysia Sdn. Bhd. Unit 10-6, Level 10, Menara MBMR, No.1, Jalan Syed Putra, 58000 Kuala Lumpur.	Pre-filled Syringe with Needle	Eranfu Fulvestrant Solution for Injection, 250 mg/5 mL (Safepac Prefilled Syringes with Safety Needles)	Schott Poonawalla Private Limited, Survey No.606/P,606/1,2,3,608/P- 1,608/2,609/5/6/2,609/1,60 9/5/6,610/1 and 610/9, Village Umarsadi, Taluka Pardi, Valsad - 396125, India.	(4) dlm.MDA 600-1/6/22 JLD 41	1/16/2024
35	Healol Pharmaceutical Sdn. Bhd. 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, W.P Kuala Lumpur.	Pre-filled Syringe	Ahrasin (Adalimumab Solution for Injection 0.8mL:40mg)	Becton Dickinson de México, S.A.de C.V Aut. méxico-Querétaro. KM.37.5 Parque Industrial Cuamatla, Cuantitlan Izcalli, Estado de méxico.C.P. 54730, México.	(4) dlm.MDA 600-1/6/22 JLD 48	13/3/2024
36	Eucogen Sdn. Bhd. No 6A, Jalan Sungai Burung U32/U, Bukit Rimau, Seksyen 32, 40460 Shah Alam, Selangor.	Pre-filled Syringe with Needle	TERATECT Prefilled Syringe INJ.(syringe)	SCHOTT Achweiz AG St. Josefen-Straße 20, 9001 St. Gallen Postaut, Switzerland.	(2) dlm.MDA 600-1/6/22 JLD 48	13/3/2024
37	Sandoz Products Malaysia Sdn. Bhd.	Pre-filled Syringe with Needle	Hyrimoz (Pre-filled Syringe with Delta Autoinjector)	1- BD Medical Pharmaceutical Systems 11, rue Aristide Bergès	(4) dlm.MDA 600-1/6/22 JLD 50	26/3/2024

	Unit 1202, Level 12, Uptown 1, No. 1, Jalan SS 21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor.			B.P. 4, F-38801 Le Pont de Claix, France. 2- Scandinavian Health Ltd. No. 136 Kuo Sheng 2nd Street, Taoyuan City, 330, Taiwan.		
38	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe	Fluarix Tetra Influenza Vaccine	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	4) dlm.MDA 600-1/6/22 JLD 63	8/10/2024
39	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe	Infanrix Hexa Vaccine	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 63	8/10/2024
40	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Infanrix-IPV+Hib	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(4) dlm.MDA 600-1/6/22 JLD 69	23/10/2024
41	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Synflorix Vaccine	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico.	(2) dlm.MDA 600-1/6/22 JLD 70	23/10/2024

				2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.		
42	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Priorix-Tetra Powder	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(4) dlm.MDA 600-1/6/22 JLD 70	23/10/2024
43	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Priorix Vaccine (MMR)	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 69	23/10/2024
44	Lundbeck Malaysia Sdn. Bhd. A-05-01 Oasis Square Jalan PJU 1A/7A Ara Damansara 47301 Petaling Jaya, Selangor Darul Ehsan.	TopPac® Pre-filled Syringe and SurGuard® 3 Safety Needle	Abilify Asimtufii 960 mg Prolonged-release Suspension for Injection in Pre-filled Syringe (with 22 gauge, 1.5 inch (38 mm) and 21 gauge, 2 inch (51 mm) SurGuard® 3 Safety Needle)	1- Terumo (Philippines) Corporation 124 East Main Avenue, Laguna Technopark, Binan, Laguna, Philippines 4024. 2- SCHOTT Pharma Schweiz AG St. Josefen-Straße 20, 9001 St. Gallen, Switzerland.	(2) dlm.MDA 600-1/6/22 JLD 55	14/6/2024
45	Merck Sdn. Bhd. Level 3, Menara Sunway Annexe, Jalan Lagoon Timur, Bandar Sunway, 46150 Petaling Jaya, Selangor.	Pre-filled Syringe	Ovidrel 250 mcg/ 0.5mL Solution for injection in Pre-filled Syringe	Becton Dickinson France SAS BD Medical-Pharmaceutical System BDM-PS Campus 11, rue Aristide Berges, BP 4, LE PONT-DECLAIX CEDEX, 38801, France.	(2) dlm.MDA 600-1/6/22 JLD 51	26/3/2024
46	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800	Pre-filled Syringe	Varilrix Vaccine	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico	4) dlm.MDA 600-1/6/22 JLD 62	8/10/2024

	Petaling Jaya, Selangor.			C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.		
47	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe	Engerix B-10 Junior Dose Suspension for Injection	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 64	8/10/2024
48	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe	Engerix B-20 Adult Dose Suspension for Injection	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 65	8/10/2024
49	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Cervarix Suspension for Injection	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(4) dlm.MDA 600-1/6/22 JLD 66	23/10/2024
50	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe and Needle	Havrix Junior 720	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson	(2) dlm.MDA 600-1/6/22 JLD 67	23/10/2024

				Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.		
51	GlaxoSmithKline Pharmaceutical Sdn. Bhd. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe	Havrix 1440	1- Becton Dickinson de Mexico S. A de C. V Autopista Mexico Queretaro Km. 37.5 Complejo industrial Cuamatla, Cuautilan, Izcalli, Estado de Mexico C.P.54730 Mexico. 2- Becton Dickinson Hungary Kft. Uveggyar ut 3., H – 2851 Kornye, Hungary.	(2) dlm.MDA 600-1/6/22 JLD 65	8/10/2024

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