

**ENDORSED DRUG-MEDICAL DEVICE PRODUCTS 2024**

NO.	APPLICANT DETAILS	DEVICE NAME	PRODUCT NAME	NAME AND ADDRESS OF DEVICE MANUFACTURER	EL REFERENCE NUMBER	EL RELEASE DATE
1	<b>Zuellig Pharma Sdn. Bhd.</b> No. 15 Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.	Pre-filled Pen (Autoinjector)	Taltz 80 mg Solution for Injection in Pre-filled Pen	1- Eli Lilly and Company Pharmaceutical Delivery System Lilly Corporate Center, Indianapolis, IN 46285, USA.  2- 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 73	28/11/2024
2	<b>Zuellig Pharma Sdn. Bhd.</b> No. 15 Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.	Pre-filled Syringe with Needle	Taltz 80 mg Solution for Injection in Pre-filled Syringe	1- Eli Lilly and Company Pharmaceutical Delivery System Lilly Corporate Center, Indianapolis, IN 46285, USA.  2- Becton Dickinson France S.A.S Pharmaceutical Systems 11 rue Aristide Berges, Le Pont-de-Claix, 38800, France.	(2) dlm.MDA 600-1/6/22 JLD 74	28/11/2024
3	<b>Biocon Sdn. Bhd.</b> No.1 Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 792000, Iskandar Puteri, Johor.	Olaf Autoinjector Pen	Nepexto 50 mg/mL Solution for Injection in Prefilled Pen (Olaf Autoinjector Pen)	Scandinavian Health Ltd. No. 136, Kuo Sheng 2nd Street Taoyuan Dist., Taoyuan City, 330, Taiwan.	(2) dlm.MDA 600-1/6/22 JLD 56	21/6/2024
4	<b>Ranbaxy (Malaysia) Sdn. Bhd.</b> A SUN PHARMA Company, 21-13, Level 21, Q Sentral, Jalan Sentral 2, 50470, Kuala Lumpur.	Pre-filled Pen (TERISUN 250MCG/ML SOLUTION FOR INJECTION, 2.4ML PRE-FILLED PEN)	Terisun Teriparatide Acetate Pen Injector	1- CC Biotechnology Corporation No. 68, Gongye 5th Rd. Annan Dist., Tainan City, Taiwan.  2- Schott Poonawalla Private Limited SurveyNo.606/P,606/1,2,3, 608/P-1,608/2 609/5/6/2,609/1,609/5/6,61 0/1 and 610/9, Costal Highway, Village: Umarsadi Taluka - Pardi, District- Valsad 396125, India.	(4) dlm.MDA 600-1/6/22 JLD 49	24/4/2024
5	<b>Kalbe Malaysia Sdn. Bhd.</b> Suite 2A-3-2, Block 2A, Plaza Sentral, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur.	EZ-fill® Staked Needle Syringe Assembled with RNS / NS	EFESA	Nuova Ompi S.r.l. Unipersonale Via Molinella, 17 35017 Piombino Dese (PD) Italy.	(4) dlm.MDA 600-1/6/22 JLD 58	17/7/2024

6	<b>GlaxoSmithKline Pharmaceutical Sdn. Bhd.</b> HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.	Pre-filled Syringe with Needle	Bexsero Suspension for Injection	1- Terumo Europe N.V. Interleuvenlaan, 403001 Leuben, Belgium  2- Becton Dickinson Hungary Kft. Uveggyar ut 3, H - 2851 Kornye Hungary.  3- Becton Dickinson de Mexico S.A. de C.V, K.M. 37.5 Autopista Mexico - Queretaro, 54740 Cuautitian, Izcalli, Estado de Mexico, Mexico.	(2) dlm.MDA 600-1/6/22 JLD 66	23/10/2024
7	<b>Ferring Sdn. Bhd.</b> 21-6, Block B, Jaya One, No 72A, Jalan Profesor Diraja Ungku Aziz, 46200 Petaling Jaya Selangor.	Pre-filled Syringe with Needle	Decapeptyl® 0.1mg Injection	Becton Dickinson France SAS, BD Medical-Pharmaceutical System, BDM-PS Manufacturing, 11, rue Aristide Berges, BP 4, LE PONT-DE-CLAIX CEDEX, 38801, France.	(2) dlm.MDA 600-1/6/22 JLD 50	24/4/2024
8	<b>Medispec (M) Sdn. Bhd.</b> B-1-07, Block B, Jalan SS 25/22, Mayang Avenue, Taman Mayang, 47301 Petaling Jaya, Selangor.	Pre-filled Syringe	Fulvestrant Seacross 250 mg Solution for Injection in Pre-filled Syringe	Shandong Wego Prefills Pharmaceutical Packaging Co., Ltd. No. 10 Weigo Road, High-Tech Industrial Development Zone, Weihai, Shandong, China 264210.	(4) dlm.MDA 600-1/6/22 JLD 55	9/5/2024
9	<b>Novo Nordisk Pharma (Malaysia) Sdn. Bhd.</b> Menara 1 Sentrum, Level 16, No 201, Jalan Tun Sambanthan 50470 Kuala Lumpur, W. P. Kuala Lumpur.	Pen-injector for Concizumab (PDS290 Pen-injector)	Alhemo®	Novo Nordisk AS Novo Allé, DK-2880 Bagsvaerd, Denmark.	(4) dlm.MDA 600-1/6/22 JLD 57	4/7/2024
10	<b>Sanofi-aventis (Malaysia) Sdn. Bhd.</b> Unit TB-18-1, Level 18, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, 46200, Petaling Jaya, Selangor.	Pre-filled Syringe with Needle	Beyfortus Solution for injection in Pre-filled Syringe (100mg/ 1.0mL)	Becton Dickinson France SAS BD Medical-Pharmaceutical Systems BDM-PS Manufacturing 11, rue Aristide Bergès, BP 4 LE PONT-DE-CLAIX CEDEX 38801 France.	(2) dlm.MDA 600-1/6/22 JLD 59	28/11/2024
11	<b>Sanofi-aventis (Malaysia) Sdn. Bhd.</b> Unit TB-18-1, Level 18, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, 46200, Petaling Jaya, Selangor.	Pre-filled Syringe with Needle	Beyfortus Solution for injection in Pre-filled Syringe (50mg/ 0.5mL)	Becton Dickinson France SAS BD Medical-Pharmaceutical Systems BDM-PS Manufacturing 11, rue Aristide Bergès, BP 4 LE PONT-DE-CLAIX CEDEX 38801 France.	(4) dlm.MDA 600-1/6/22 JLD 59	28/11/2024

12	<b>Sabah Oxygen Sdn. Bhd.</b> Lot No. 30, Jalan 2A KKIP Timur, Industrial Zone 12 (IZ12), Kota Kinabalu Industrial Park (KKIP), 88460 Kota Kinabalu, Sabah.	Medical Gas Cylinder Fitted with Valve	1- Sabah Oxygen Medicinal Oxygen 100% v/v 2- Sabah Oxygen Medical Carbon Dioxide Gas 99.5% v/v 3- Sabah Oxygen Medical Air	Sabah Oxygen Sdn Bhd Lot No. 30, Jalan 2A KKIP Timur, Industrial Zone 12 (IZ12), Kota Kinabalu Industrial Park (KKIP), 88460 Kota Kinabalu, Sabah.	(2) dlm.MDA 600-1/6/22 JLD 60	15/8/2024
13	<b>MERCK SHARP &amp; DOHME (MALAYSIA) SDN. BHD.</b> B-22-1 & B-22-2 The Ascent Paradigm, No. 1 Jalan SS7 / 26A, Kelana Jaya, 47301 Petaling Jaya, Selangor Darul Ehsan.	TERUMO SurGuard3 Safety Hypodermic Needle	WINREVAIR™	Terumo (Philippines) Corporation 124 East Main Avenue, Laguna Technopark, Binan, Laguna, Philippines, 4024.	(4) dlm.MDA 600-1/6/22 JLD 56	4/7/2024
14	<b>Novo Nordisk Pharma (Malaysia) Sdn. Bhd.</b> Menara 1 Sentrum, Level 16 No. 201, Jalan Tun Sambanthan, 50470 Kuala Lumpur.	Pen-injector for Icodec	Awikli®	Novo Nordisk AS Novo Allé, DK-2880 Bagsvaerd, Denmark.	(2) dlm.MDA 600-1/6/22 JLD 58	4/7/2024
15	<b>Abbott Laboratories (M) Sdn. Bhd.</b> 27-02, Level 27, Imazium, No. 8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.	Type 1 Glass Syringe Barrel with Needle	Influvac Tetra Suspension for Injection in Pre-filled Syringe	Abbott Biologicals B, V, Veerweg 12, 8121AA, Olst, The Netherlands.	(4) dlm.MDA 600-1/6/22 JLD 78	15/1/2025
16	<b>Duopharma (M) Sdn. Bhd.</b> Lot 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor.	Pre-filled Syringe: 1- BD HYPAK SCF 1MLL 27GA 1/2 IN-5B RNS7974 PPL 2- HYPAK TSCF1MLL 4023/50 FLUROTEC EV LID 3- BD HYPAK PR1MLL PP WHITE	ERYSAA® Prefilled Syringe 4,000 IU / 0.4 mL ERYSAA® Prefilled Syringe 2,000 IU / 0.5 mL	1- Becton Dickinson France S.A.S. Pharmaceutical Systems 11 rue Aristide Berges Le Pont-de-Claix 38800 France.  2- Becton Dickinson de México, S.A de C.V Aut. México-Querétaro.Km. 37.5 Parque industrial Cuamatla Cuautitlán Izcalli Estado de México C.P.54730 Mexico.	(4) dlm.MDA 600-1/6/22 JLD 75	20/12/2024
17	<b>Biocon Sdn. Bhd.</b> No.1 Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 792000, Iskandar Puteri, Johor.	Pre-filled Syringe (0.5 mL and 1 mL)	1- Yesintek 45 mg/ 0.5 mL Solution for Injection in Pre-filled Syringe 2- Yesintek 90 mg/ 1 mL Solution for Injection in pre-filled Syringe	BD Medical-Pharmaceutical Systems 11, Rue Aristide Berges BP 4 38800 Le Pont-de Claix France	(2) dlm.MDA 600-1/6/22 JLD 73	28/11/2024

18	<b>Johnson &amp; Johnson Sdn. Bhd.</b> Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 46150 Petaling Jaya, Selangor.	One-Press	1- Stelara One-Press 45mg/ 0.5mL Solution for Injection 2- Stelara One-Press 90mg/ 1.0mL Solution for Injection	Becton Dickinson France SAS BD Medical-Pharmaceutical Systems BDM-PS Manufacturing 11, rue Aristide Berges, BP 4, Le Pont-de-Claix Cedex, 38801, France.	(4) dlm.MDA 600-1/6/22 JLD 77	20/12/2024
19	<b>Gas Pantai Timur Sdn. Bhd.</b> Lot 300733 & 300734, Kawasan Perindustrian Gopeng, 31600 Gopeng, Perak.	Medicinal Cylinder and Valve	1- GPT Medicinal Oxygen 100% v/v 2- GPT Medicinal Air 100% v/v	Gas Pantai Timur Sdn. Bhd. Lot 300733 & 300732, Kawasan Perindustrian Gopeng, 31600 Gopeng, Perak.	(2) dlm.MDA 600-1/6/22 JLD 71	12/11/2024
20	<b>Unimed Sdn. Bhd.</b> No. 2, Jalan Perindustrian Desa Aman 1A, Taman Perindustrian Desa Aman, 52200 Kuala Lumpur, W. P. Kuala Lumpur.	BD HYPAK (TD 001) Syringe Barrel Type 1 Borosilicate Glass Pre-filled Syringe with Needle	Fresly Fondaparinux Sodium 2.5mg/ 0.5mL Solution for Injection in Pre-filled Syringe	Becton Dickinson Medical Pharmaceutical System (BD) 11 rue Aristide Bergès, 38801 Le Pont de Claix, France	(2) dlm.MDA 600-1/6/22 JLD 77	20/12/2024
21	<b>Zuellig Pharma Sdn. Bhd.</b> No. 15 Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.	Pre-filled Pen (Autoinjector)	Ebglyss 250mg Solution for Injection in Pre-filled Pen	Eli Lilly and Company Lilly Corporate Centre, Indianapolis, Indianac46285, USA	(4) dlm.MDA 600-1/6/22 JLD 74	28/11/2024
22	<b>Celltrion Healthcare Malaysia Sdn. Bhd.</b> Unit 32-01, Level 32 Tower B, The Vertical Corporate Tower, Avenue 10, Bangsar South, No. 8, Jalan Kerinchi, 59200 Kuala Lumpur, W. P. Kuala Lumpur.	Pre-filled Syringe with Safety Guard (PFS-S)	1- Omlyclo 75mg/ 0.5mL solution for injection in pre-filled syringe 2- Omlyclo 150mg/ 1.0mL solution for injection in pre-filled syringe	Syringe with needle: BD France SAS  Safety guard: BD Hungary	(2) dlm.MDA 600-1/6/22 JLD 62	19/9/2024
23	<b>BSV BIOSCIENCE MALAYSIA SDN. BHD.</b> 3, Jalan 19/1, 46300 Petaling Jaya, Selangor.	Pen-injector (with Needle)	1- FOLIGRAF Recombinant Human Follicle Stimulating Hormone Solution for Injection 450 iu/ 0.75 mL (33 mcg/ 0.75 mL) in Multidose Pre-filled Pen 2- FOLIGRAF Recombinant Human Follicle Stimulating Hormone Solution for Injection 900 iu/ 1.5 mL (66 mcg/ 1.5 mL) in Multidose Pre-filled Pen	Becton Dickinson France SAS BD Medical-Pharmaceutical Systems , BDM-PS Manufacturing , 11, rue Aristide Bergès, BP 4 , LE PONT-DE-CLAIX CEDEX , 38801 , France.	(2) dlm.MDA 600-1/6/22 JLD 78	15/1/2025
24	<b>Duopharma (M) Sdn. Bhd.</b> Lot 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya,	Pre-filled Syringe: 1- BD HYPAK SCF 1MLL 27GA 1/2 IN-5B RNS7974 PPL	ERYSAA® Prefilled Syringe 6,000 IU / 0.6 mL ERYSAA® Prefilled Syringe 10,000 IU / 1.0 mL	1- Becton Dickinson France S.A.S. Pharmaceutical Systems 11 rue Aristide Berges Le Pont-de-Claix 38800 France.	(2) dlm.MDA 600-1/6/22 JLD 76	20/12/2024

	41200 Klang, Selangor.	2- HYPAK TSCF1MLL 4023/50 FLUROTEC EV LID 3- BD HYPAK PR1MLL PP WHITE		2- Becton Dickinson de México, S.A de C.V Aut. México- Querétaro.Km. 37.5 Parque industrial Cuamatla Cuautitlán Izcalli Estado de México C.P.54730 Mexico.		
25	<b>Y.S.P. Industries (M) Sdn. Bhd.</b> 3, 5, & 7, Jalan P/7, Seksyen 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor.	Vaccine Syringe Barrel with Needle	AdimFlu-S	1- Becton Dickinson de México S.A de C.V Autopista Mexico Queretaro Km. 37.5 Complejo Industrial Cuamatla, Cuautilan, Izcalli, Estado de México, C.P.54730, Mexico.  2- Nuova Ompi S.r.l. Unipersonale Via Molinella, 17, 35017 Piombino Dese (PD), Italy.	(2) dlm.MDA 600-1/6/22 JLD 75	20/12/2024
26	<b>Pharmaniaga LifeScience Sdn. Bhd.</b> Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor.	Pen-injector (with Needle)	Basalin ElasPen 100 Units/mL Solution for Injection	Gangan Medical Technology Jiangsu Co., Ltd. 1st - 4th Floor, Building G130, Fifth Phase of Standard Workshop, China Medical City, Taizhou, 225300 Jiangsu, China.	(2) dlm.MDA 600-1/6/22 JLD 72	24/11/2024
27	<b>Medispec (M) Sdn. Bhd.</b> B-1-07, Block B, Jalan SS 25/22, Mayang Avenue, Taman Mayang, 47301 Petaling Jaya, Selangor.	Pen-injector	Liraglutide Injection	Ypsomed AG Weissensteinstrasse 26 4503 Solotrum Switzerland.	(2) dlm.MDA 600-1/6/22 JLD 79	15/1/2025
28	<b>Biocon Sdn. Bhd.</b> No.1 Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 792000, Iskandar Puteri, Johor.	Pre-filled Syringe with Needle	BOSAYA Denosumab (rDNA Origin) Solution for Injection in Pre-filled Syringe 60 mg/mL	BD Medical, Phramaceutical Systems, 920 East 19th Street Columbus, NE 68601, USA.	(4) dlm.MDA 600-1/6/22 JLD 65	28/11/2024
29	Kalbe Malaysia Sdn Bhd Suite 2A-3-2, Block 2A, Plaza Sentral, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur	Pen-injector (XLB02A)	EZELIN (Insulin Glargine Injection, 100 units/mL Solution for Injection in Pre-filled Pen)	Gangan Medical Technology Jiangsu Co. Ltd. 1st-4th Floor, Building G130, Fifth Phase of Stabdard Workshop, China Medical City, Taizhou, 225300 Jiangsu, P. R. China.	(4) dlm.MDA 600-1/6/22 JLD 79 16/1/2024	16/1/2025

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