

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 20/08/2018

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURE R	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
MDA/DM/2018/37	KLS Martin SE Asia Sdn Bhd	Electrosurgical Unit with handpieces, Details see Letter	KLS Martin	Gebrüder Martin GmbH & Co. KG Germany	Internal show event in KLS Martin Malaysia's show room.	KLS Martin Malaysia Sdn. Bhd. No. 1193, Lorong Perindustrian Bukit Minyak 11, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang.	25 June – 24-Sep-18
MDA/DM/2018/41	DiagnostiCare Sdn Bhd	VITROS Immunodiagnostic Products C-Peptide Reagent Pack	VITROS	Ortho-Clinical Diagnostics	Product Presentation	Mahkota Medical Centre, Melaka Regency Specialist Hospital, Johor KPJ Selangor	23 – 27 July 2018, 13 – 17 Aug 2018, 3 -7 Sept 2018
MDA/DM/2018/42	Quantarad Technologies Sdn Bhd.	Automatic CO2 Insufflator - Virtual Colonoscopy Insufflator	VIMAP TECHNOLOGIES	Ortho-Clinical Diagnostics UK	Demonstration	Hospital Sungai Buloh	24 June – 23 September 2018
MDA/DM/2018/49	Olympus (Malaysia) Sdn. Bhd.	Various Olympus Brand Surgical Instruments (55 items)	Olympus	OLYMPUS WINTER & IBE GMBH	1st International Lateral Skull based & Functional Endoscopic Sinus Surgery Workshop 8th Ipoh Endoscopic Sinus Surgery Course	Putrajaya Marriott Hotel Anatomy Dissection Hall, University Kuala Lumpur, Royal College of Medicine Perak.	23 - 26 July 2018 & 5-7 October 2018
-	-	Various Olympus Brand, Microdebriders devices (34 items)	Olympus	GYRUS ACMI, INC.	-	-	-
MDA/DM/2018/55	JJSV Manufacturing Malaysia Sdn Bhd	LipiFlow Thermal Pulsation System and Accessories	TearScience®	Tear Science	Presentation/ Explanation to Healthcare Professionals	Dr. Peter Kong Specialist Eye Centre ISEC Sdn. Bhd. USJ Eye Specialist Centre	10 July 2018 – 10 October 2018
-	-	LipiView Ocular Surface Interferometer	TearScience®	Tear Science	-	-	-
-	-	LipiView II Ocular Surface Interferometer	TearScience®	Tear Science	-	-	-
-	-	LipiScan Dynamic Meibomian Imager	TearScience®	Tear Science	-	-	-
-	-	Meibomian Gland Evaluator	TearScience®	Tear Science	-	-	-
-	-	Meibomian Gland Evaluator	TearScience®	Tear Science	-	-	-
MDA/DM/2018/59	Dentsply Sirona Malaysia Sdn. Bhd.	DAC UNIVERSAL (Cleans, Lubricates And Disinfects) (95 Components)	DAC Universal	Sirona Dental A/S, Rho 10, 8382 Hinnerup, Denmark.	Exhibition (MIDEC) 45th APDSA Annual Congress 17th Penang Dental Congress	Kuala Lumpur Convention Centre International Medical University (IMU) Equatorial Hotel	20-22 July 2018, 6-10 August 2018, 12-15 October 2018

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MDA/DM/2018/60	AJ Research & Pharma Sdn Bhd	AC-NORM Medilike Effect 1 cream	FREZYDERM	FREZYDERM S.A	Presentation Presentation Presentation Presentation In house evaluation	ME Clinic, Kuala Lumpur Prinz Medical Clinic, Kuala Lumpur MAC Clinic, Kuala Lumpur Klinik Dr Lo, Kajang, Selangor Klinik Foo, Johor AJ Research & Pharma Sdn. Bhd, Kuala Lumpur	23 July 2018 – 22 October 2018
-	-	AC-NORM Medilike Effect 2 cream	FREZYDERM	FREZYDERM S.A	-	-	-
-	-	AC-NORM Medilike Effect 3 cream	FREZYDERM	FREZYDERM S.A	-	-	-
MDA/DM/2018/62	Nexgen Medical Sdn Bhd	CRESPINE® GEL+, Injectable Implant for the treatment of Osteoarthritis	CRESPINE® GEL+	BioPolymer GmbH & Co. KG, Germany	Presentation/ Explanation to Medical Doctors	KPJ Hospital Pantai Hospital Columbia Asia Hospital	9 July 2018 – 8 October 2018
MDA/DM/2018/66	Biomarketing Services (M) Sdn Bhd	Integrated Antibody Identification Software (IH- AbID)	BIORAD	Diamed GMBH	Demonstration	Hospital Ampang Sunway Medical Centre HUKM	01-Aug-18, 15-Aug-18, 01-Sep-18
-	-	Ab Titration Kit	BIORAD	Diamed GMBH	-	-	-
-	-	IH Web	BIORAD	Diamed GMBH	-	-	-
MDA/DM/2018/68	DiagnostiCare Sdn Bhd	Blood Grouping Reagents Anti A (Anti-ABO1) (Monoclonal) Anti-B (Anti- ABO2) (Monoclonal) Anti A,B (Anti-AB03) (Monoclonal) Anti-D (Anti- RH1) (Monoclonal) Anti- CDE (Anti-RH1,2,3) (Monoclonal) Control Ortho BioVue (ABO-Rh Grouping Cassette)	ORTHO	Ortho-Clinical Diagnostics, UK	Product presentation	Sunway Medical Centre	1st August – 30th August 2018
-	-	Anti-Human Globulin Anti- IgG (Rabbit) Anti-Human Globulin Anti-C3b, -C3d (Monoclonal) Control BioVue System (DAT/IDAT Cassette)	ORTHO	Ortho-Clinical Diagnostics, UK	-	-	-
-	-	Blood Grouping Reagents Anti-D (Anti-RH1) (Monoclonal) Anti-C (Anti- RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti-c (Anti-RH4) (Monoclonal) Anti-e (Anti- RH5) (Monoclonal) Control Ortho BioVue (Rh-hr Cassette)	ORTHO	Ortho-Clinical Diagnostics, UK	-	-	-

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MDA/DM/2018/71	Duerr Dental South East Asia Sdn Bhd	Duerr Dental VistaSoft Imaging Software	Duerr Dental	Durr Dental SE	Malaysia International Dental Exhibition and Conference (MIDEC 2018) MDA Northern Zone 17th Penang Dental Congress	KLCC Equatorial Hotel Penang	20 - 22 July 2018 & 12 - 14 October 2018
MDA/DM/2018/73	Straits Scientific (M) Sdn Bhd	Vision ESR Analyzer	YHLO	Shenzhen YHLO Biotech	Demonstration	Columbia Asia Hospital Seremban	1st Sept – 30th Sept 2018
-	-	Vision Master Dongle	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash 1800-A	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-FSH	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	AMH	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	LH	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	HCG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-Prolactin	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-DHEA-S	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-FT4	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-FT3	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-TSH	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-AFP	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-CEA	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-CA 124	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-CA 19-9	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-Free PSA	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-Total PSA	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-Toxo IgG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash- Toxo IgM	YHLO	Shenzhen YHLO Biotech	-	-	-

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-	-	iFlash-Rubella IgG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash- Rubella IgM	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-CMV IgG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash- CMV IgM	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-HSV-1 IgG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash- HSV-1 IgM	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-HSV-2 IgG	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash- HSV-2 IgM	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	iFlash-PCT	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Wash Buffer	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Pre-Trigger Solution	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Trigger Solution	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Reaction Cuvette	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Waste Box	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Tumor Marker Multi Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Immunoassay Multi Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	AMH Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	PCT Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Toxo IgG Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	CMV IgG Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	CMV IgM Control	YHLO	Shenzhen YHLO Biotech	-	-	-
-	-	Rubella IgG Control	YHLO	Shenzhen YHLO Biotech	-	-	-
MDA/DM/2018/78	Abbott (Alere Health Sdn Bhd)	AlereTM i Instrument	AlereTM	Alere Scarborough, Inc.	Presentation & product demo	Sunway Medical Centre Abbott (Alere Health SB) Abbott (Alere Health SB)	27th August 2018, 7th September 2018, 5th October 2018

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MDA/DM/2018/80	PHILIPS Malaysia Sdn Berhad	<i>BiPAP V30 Auto ventilator</i>	Philips - Respironics	Respironics Inc, USA	6th World Congress of SIVA-TCI 2018 (Society of Intra Venous Anaesthesia-Target Controlled Infusion) Annual Scientific Meeting on Intensive Care (ASMIC) 2018	Kuala Lumpur Convention Center (KLCC) Shangri-La Hotel, Kuala Lumpur	15 - 18 August 2018 & 20 - 23 September 2018
MDA/DM/2018/81	ARQon Medtech Sdn. Bhd.	3D HD Video Recorder	Sony	Sony Corporation, Tokyo Japan	Demo – Connection compatibility	PTj Nadi IT, University Malaya Medical Centre	13th August – 31st Oct 2018
MDA/DM/2018/82	BioMerieux Malaysia Sdn Bhd	Microbial Identification System VITEK® 2 XL; and VITEK® Cards	BioMerieux	bioMérieux, Inc., USA	Product Presentation	Lablink (M) Sdn. Bhd. Kuala Lumpur.	20th August – 20th Sept 2018
MDA/DM/2018/83	Mandarin Opto-Medic Sdn Bhd	1. ROSE K2 Trial Set Menicon Z; and 2. ROSE K2 Extra Limbal XL Trial Set Menicon Z	Menicon	Menicon Ltd	Presentation product	Hospital Sungai Buloh Hospital Kuala Lumpur IIUM Medical Center PPUKM (Hos Canselor Tuanku Muhriz)	13th Aug – 27th Aug 2018
MDA/DM/2018/84	Foresight Industries Sdn Bhd	Silgine Silver Alginate Wound Dressing	Choice	Foresight Industries Sdn Bhd	RENALCARE : Technician Program Global Wound Conference 2018	Pusat Dialisis Shah Alam, Bukit Jelutong Royal Chulan, Kuala Lumpur	16th Aug – 23rd Aug 2018 & 21st Sept – 23rd Sept 2018
-	-	Algine Calcium Alginate Wound Dressing	Choice	Foresight Industries Sdn Bhd	-	-	-
-	-	Silicone Tape	Choice	Foresight Industries Sdn Bhd	-	-	-
-	-	Hemodialysis Machine	WESLEY BIOTECH	Chengdu Wesley Biotech Co., Ltd	-	-	-
-	-	Dialyzer Reprocessing Machine	WESLEY BIOTECH	Chengdu Wesley Biotech Co., Ltd	-	-	-
MDA/DM/2018/85	Medi-Life (M) Sdn Bhd	Automatic Cutting Needle - ACN™ Biopsy Needles, 18ga x 20cm	ACN™	Argon Medical Devices, Inc, Texas USA	Presentation product - TRUS biopsy cases Presentation product - TRUS biopsy cases	Hospital Serdang Pusat Pengimejan Diagnostik Nuklear, UPM	5th Sept 2018 12th Sept 2018