

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
MDA/DM/2019/022	OTICON MALAYSIA SDN. BHD.	ZR9 MNR, 2.4G NFM PB SABE/MAC DEMO	ZR9 MNR, 2.4G NFM PB SABE/MAC DEMO	BERNAFON AG	PRODUCT DEMONSTRATION	HOSPITAL AROUND MALAYSIA	01/07/2019 Period of Demo: 18/06/2019 – 16/09/2019
-	-	ZR7 MNR, 2.4G NFM PB SABE/MAC DEMO	ZR7 MNR, 2.4G NFM PB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR5 MNR, 2.4G NFM PB SABE/MAC DEMO	ZR5 MNR, 2.4G NFM PB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR3 MNR, 2.4G NFM PB SABE/MSIL DEMO	ZR3 MNR, 2.4G NFM PB SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	ZR1 MNR, 2.4G NFM PB SABE/MSIL DEMO	ZR1 MNR, 2.4G NFM PB SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	ZR9 MNR T, 2.4G NFM DPB SABE/MAC DEMO	ZR9 MNR T, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR7 MNR T, 2.4G NFM DPB SABE/MAC DEMO	ZR7 MNR T, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR5 MNR T, 2.4G NFM DPB SABE/MAC DEMO	ZR5 MNR T, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR3 MNR T, 2.4G NFM DPB SABE/MSIL DEMO	ZR3 MNR T, 2.4G NFM DPB SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	ZR1 MNR T, 2.4G NFM DPB SABE/MSIL DEMO	ZR1 MNR T, 2.4G NFM DPB SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	ZR9 B 105, 2.4G NFM DPB SABE/MAC DEMO	ZR9 B 105, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR7 B 105, 2.4G NFM DPB SABE/MAC DEMO	ZR7 B 105, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR5 B 105, 2.4G NFM DPB SABE/MAC DEMO	ZR5 B 105, 2.4G NFM DPB SABE/MAC DEMO	BERNAFON AG	-	-	-
-	-	ZR3 B 105, 2.4G NFM DPB SABE/MSIL DEMO	ZR3 B 105, 2.4G NFM DPB SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	ZR1 B 105, 2.4G NFM SABE/MSIL DEMO	ZR1 B 105, 2.4G NFM SABE/MSIL DEMO	BERNAFON AG	-	-	-
-	-	SALES PACK, OASIS NXT USB (2018.2 BERNAFON VAR)	SALES PACK, OASIS NXT USB (2018.2 BERNAFON VAR)	BERNAFON AG	-	-	-
MDA/DM/2019/030	CREATIVE MIND VENTURE SDN BHD	VITALZ-X	VITALZ-X	CHART TECHNO SOLUTIONS PVT-LTD	DEMONSTRATION	KLINIK KITA PANDAN JAYA, KLINIK MEDIVRON	12/08/2019 Period of Demo : 15/07/2019 – 04/10/2019
MDA/DM/2019/051	EASMED SDN BHD	XION MATRIX E	XION	XION GMBH	11TH MALAYSIAN INTERNATIONAL ORL-HNS CONGRESS & 39TH ANNUAL GENERAL MEETING OF THE MSO-HNS	ROYALE CHULAN KUALA LUMPUR, MALAYSIA	20/06/2019 Period of Demo : 01/06/2019 – 30/08/2019
MDA/DM/2019/052	GE HEALTHCARE SDN. BHD	VERSANA PREMIER ULTRASOUND SYSTEM	GE / VERSANA	GE MEDICAL SYSTEMS (CHINA) CO., LTD.	22ND FAMILY MEDICINE SCIENTIFIC CONFERENCE	BORNEO CONVENTION CENTRE KUCHING KUCHING SARAWAK	30/06/2019 Period of Demo : 01/06/2019 – 30/08/2019

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
MDA/DM/2019/053	ACUTEST SYSTEMS (M) SDN BHD	CHEMISTRY ANALYZER POINTCARE M3	POINTCARE M3	MNCHIP	EVALUATION AT CUSTOMER SITE	MAKMAL PATOLOGI, HOSPITAL AMPANG	19/08/2019 Period of Demo : 11/08/2019 – 09/11/2019
MDA/DM/2019/058	ROCHE DIAGNOSTICS (M) SDN. BHD.	COBAS B 123 <4> POC SYSTEM	ROCHE	ROCHE DIAGNOSTICS GMBH, SANDHOFER STRASSE 116, 68305 MANNHEIM, GERMANY	EXPLANATION	HOSPITAL KUALA LUMPUR, PATHOLOGY DEPARTMENT	01/07/2019 – 01/08/2019 Period of Demo : 01/07/2019 – 29/09/2019
-	-	COBAS B 123 AUTOQC PACK (TRI-LEVEL)	ROCHE	ROCHE DIAGNOSTICS GMBH, SANDHOFER STRASSE 116, 68305 MANNHEIM, GERMANY	-	-	-
-	-	COBAS B 123 SENSOR CARTRIDGE BG/ISE/GLU/LAC	ROCHE	ROCHE DIAGNOSTICS GMBH, SANDHOFER STRASSE 116, 68305 MANNHEIM, GERMANY	-	-	-
-	-	COBAS B 123 FLUID PACK COOX 200	ROCHE	ROCHE DIAGNOSTICS GMBH, SANDHOFER STRASSE 116, 68305 MANNHEIM, GERMANY	-	-	-
-	-	COBAS B 123 FLUID PACK COOX 700	ROCHE	ROCHE DIAGNOSTICS GMBH, SANDHOFER STRASSE 116, 68305 MANNHEIM, GERMANY	-	-	-
MDA/DM/2019/064	UMMI SURGICAL SDN BHD	ROUND KNIFE, WITH SUCTION, ROTATIONG	227230	KARL STORZ SE & CO. KG	11TH MALAYSIAN INTERNATIONAL ORL-HNS CONGRESS & 39TH ANNUAL GENERAL MEETING OF THE MSO-HNS, 17TH INTERNATIONAL FUNCTIONAL ENDOSCOPIC SINUS SURGERY WORKSHOP, 22ND ASIAN CONGRESS OF SURGERY (CSAMM ASC 2019),	ROYALE CHULAN KUALA LUMPUR, PUSAT PERUBATAN UNIVERSITI KEBANGSAAN MALAYSIA, SHANGRI-LA HOTEL, KUALA LUMPUR, PUSAT PERUBATAN UNIVERSITI MALAYA, PUSAT PERUBATAN UNIVERSITI MALAYA	20-22/6/2019, 9 -10/7/2019, 1 - 4/8/2019, 6 - 8/8/2019 & 6 – 8/9/2019

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
					21ST UMMC ADVANCED SKULLBASE DISSECTION WORKSHOP, TMJ SURGERY - ARTHROCENTESIS & ARTHROSCOPY WORKSHOP. COLLABORATION WITH SORG		
-	-	SUCTION ELEVATOR, ROTATABLE	474010	KARL STORZ SE & CO. KG	-	-	-
-	-	INJECTION NEEDLE, MALLEABLE, 25 CM	8795N	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR SUCTION FORCEPS, 15°	461010	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR FORCEPS	842216G	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR FORCEPS	844216G	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR FORCEPS, WITH BAR, LENGTH 23 CM	844524	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR FORCEPS, ANGLED, 23 CM	844525	KARL STORZ SE & CO. KG	-	-	-
-	-	HODLING DEVICE FOR 523950	523951	KARL STORZ SE & CO. KG	-	-	-
-	-	CLEANING ADAPTOR	523952	KARL STORZ SE & CO. KG	-	-	-
-	-	HOLDING DEVICE FOR 523950	523954	KARL STORZ SE & CO. KG	-	-	-
-	-	SUCTION ELEVATOR, 19 CM	474001	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR SUCTION FORCEPS, 45°	461015	KARL STORZ SE & CO. KG	-	-	-
-	-	BIPOLAR COAGULATING FORCEPS, 19 CM	843219	KARL STORZ SE & CO. KG	-	-	-
-	-	FLUORESCEIN BLUE FILTER SYSTEM	20100032	KARL STORZ SE & CO. KG	-	-	-
-	-	FLUORESCEIN BARRIER FILTER	20100033	KARL STORZ SE & CO. KG	-	-	-
-	-	EM PATIENT TRACKER	40820086	KARL STORZ SE & CO. KG	-	-	-
-	-	EM ENDOSCOPE TRACKER, UNIVERSAL	40820150	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1-MODULE	40810020	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1 ELECTROMAGNETIC MODULE	40820020	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1 ELECTROMAGNETIC FIELD GENERATOR	40820030	KARL STORZ SE & CO. KG	-	-	-
-	-	ROBI® METAL OUTER SHEATH	38700	KARL STORZ SE & CO. KG	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	CLIP APPLICATOR	49205L	KARL STORZ SE & CO. KG	-	-	-
-	-	TWO-PEDAL FOOTSWITCH, TWO-STAGE	20012630	KARL STORZ SE & CO. KG	-	-	-
-	-	FISCH ANEURYSM NEEDLE, 20 CM	800005	KARL STORZ SE & CO. KG	-	-	-
-	-	TROCAR, 2.5 MM Ø	58702X	KARL STORZ SE & CO. KG	-	-	-
-	-	OBTURATOR, SHARP	58702XS	KARL STORZ SE & CO. KG	-	-	-
-	-	OBTURATOR, BLUNT	58702XT	KARL STORZ SE & CO. KG	-	-	-
-	-	OBTURATOR, SHARP	58706BS	KARL STORZ SE & CO. KG	-	-	-
-	-	OBTURATOR, BLUNT	58706BT	KARL STORZ SE & CO. KG	-	-	-
-	-	SHARP OBTURATOR	11578BS	KARL STORZ SE & CO. KG	-	-	-
-	-	OBTURATOR, BLUNT	11578BT	KARL STORZ SE & CO. KG	-	-	-
-	-	ALL-IN-ONE TMJ ARTHROSCOPE	11578A	KARL STORZ SE & CO. KG	-	-	-
MDA/DM/2019/066	SCHILLER ASIA PACIFIC SDN. BHD.	MEDILOG AR HOLTER	SCHILLER	SCHILLER AG	DEMONSTRATION TO HOSPITALS	AS LISTED IN THE LETTER	17/6/2019 - 15/9/2019
MDA/DM/2019/071	CORE3DCENTRES MALAYSIA SDN. BHD.	BON MAKER M-1	AUTO-TOOTH BONE GRAFT SYSTEM	KOREA DENTAL SOLUTION	MALAYSIA INTERNATIONAL DENTAL EXHIBITION & CONFERENCE (MIDEC 2019)	KUALA LUMPUR CONVENTION CENTRE	11/7/2019 – 15/7/2019 Period of Demo : 05/06/2019 – 03/09/2019
MDA/DM/2019/072	CORE3DCENTRES MALAYSIA SDN. BHD.	BON MAKER M-1	AUTO-TOOTH BONE GRAFT SYSTEM	KOREA DENTAL SOLUTION	EXHIBITION: JOURNEY IN DIGITAL DENTISTRY: FACT OR FASHION MALAYSIAN IMPLANT SYMPOSIUM	LE MERIDIEN HOTEL KUALA LUMPUR, PULLMAN BANGSAR KUALA LUMPUR	20/11/2019, 19/10/2019 - 21/10/2019 Period of Demo : 03/09/2019 – 02/12/2019
MDA/DM/2019/075	MEDTRONIC MALAYSIA SDN BHD	NTF KIT ZEISS KINEVO	9736149	MEDTRONIC NAVIGATION, INC.	NEUROSURGICAL ASSOCIATION OF MALAYSIA'S 18TH ANNUAL GENERAL MEETING & ANNUAL SCIENTIFIC MEETING 2019 (NAM AGM-ASM-2019)	SHERATON PETALING JAYA HOTEL	17/8/2019 Period of Demo: 15/07/2019 – 30/09/2019
MDA/DM/2019/077	ENHANCE DENTAL GROUP SDN BHD	PULP TESTER	VIVIDEN	DNH MEDTECH CO.	PRESENTATION FOR HOSPITAL, GOVERNMENT CLINIC & UNIVERSITY WITHIN 90 DAYS.	SELANGOR , KUALA LUMPUR	05/07/2019 Period of Demo: 21/06/2019 – 22/09/2019
MDA/DM/2019/079	KLS MARTIN SE ASIA SDN BHD	MARSAFE +, GREY, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-236-10-04	GEBRÜDER MARTIN GMBH & CO. KG	DEMO UNIT AT KLS MARTIN MALAYSIA'S SHOW ROOM BORNEO MEDICAL DEVICE	KLS MARTIN SE ASIA SDN BHD, PENANG SABAH WOMEN & CHILD HOSPITAL	28/6/2019, 4/7/2019 - 5/7/2019 Period of Demo: 28/06/2019 – 25/09/2019

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
					REPROCESSING WORKSHOP		
-	-	MARSAFE +, RED, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-246-10-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
-	-	MARSAFE +, BLUE, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-256-10-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
-	-	MARSAFE +, ORANGE, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-266-10-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
-	-	MARSAFE +, GREEN, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-276-10-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
-	-	MARSAFE +, L.GREY, 30X30X11CM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-286-10-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
-	-	MARSAFE +, BARRIER SYSTEM	KLS MARTIN/ MARSAFE®/ ARTICLE NO.: 55-292-00-04	GEBRÜDER MARTIN GMBH & CO. KG	-	-	-
MDA/DM/2019/080	ARQON MEDTECH SDN. BHD.	ITERO ELEMENT 2 BVE SYSTEM	ITERO ELEMENT 2 BVE	ALIGN TECHNOLOGY B.V.	PRODUCT DEMONSTRATION/ITERO 2 DEMO	LOCATION AS PER LETTER / IN MEDCAST SYSTEM	1/7/2019 - 29/9/2019
MDA/DM/2019/081	OTICON MALAYSIA SDN. BHD.	SIYA 1, MRITE 312 2.4G NFM PB C090	SIYA 1, MRITE 312 2.4G NFM PB C090	OTICON A/S	PRODUCT DEMONSTRATION	HEARING PARTNERS MALAYSIA (PLEASE REFER TO LIST IN MEDCAST)	1/7/2019 - 24/9/2019
-	-	SIYA 1, MINIRITE T 312 2.4G C090	SIYA 1, MINIRITE T 312 2.4G C090	OTICON A/S	-	-	-
-	-	SIYA 1, BTE 13 2.4G 85 C090	SIYA 1, BTE 13 2.4G 85 C090	OTICON A/S	-	-	-
-	-	SIYA 1, BTE 13 PP 2.4G 105 C090	SIYA 1, BTE 13 PP 2.4G 105 C090	OTICON A/S	-	-	-
-	-	SIYA 2, MRITE 312 2.4G NFM PB C090	SIYA 2, MRITE 312 2.4G NFM PB C090	OTICON A/S	-	-	-
-	-	SIYA 2, MINIRITE T 312 2.4G C090	SIYA 2, MINIRITE T 312 2.4G C090	OTICON A/S	-	-	-
-	-	SIYA 2, BTE 13 2.4G 85 C090	SIYA 2, BTE 13 2.4G 85 C090	OTICON A/S	-	-	-
-	-	SIYA 2, BTE 13 PP 2.4G 105 C090	SIYA 2, BTE 13 PP 2.4G 105 C090	OTICON A/S	-	-	-
-	-	GENO 1, MINIBTE 312 WL 85 C090	GENO 1, MINIBTE 312 WL 85 C090	OTICON A/S	-	-	-
-	-	GENO 1, MINIRITE 312 WL C090	GENO 1, MINIRITE 312 WL C090	OTICON A/S	-	-	-
-	-	GENO 1, RITE 312 WL C090	GENO 1, RITE 312 WL C090	OTICON A/S	-	-	-
-	-	GENO 1, BTE 13 WL 85 C090	GENO 1, BTE 13 WL 85 C090	OTICON A/S	-	-	-
-	-	GENO 1, BTE P 13 WL 100 C090	GENO 1, BTE P 13 WL 100 C090	OTICON A/S	-	-	-
-	-	GENO 1, BTE PP 13 WL 105 C090	GENO 1, BTE PP 13 WL 105 C090	OTICON A/S	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	GENO 2, MINIBTE 312 WL 85 C090	GENO 2, MINIBTE 312 WL 85 C090	OTICON A/S	-	-	-
-	-	GENO 2, MINIRITE 312 WL C090	GENO 2, MINIRITE 312 WL C090	OTICON A/S	-	-	-
-	-	GENO 2, RITE 312 WL C090	GENO 2, RITE 312 WL C090	OTICON A/S	-	-	-
-	-	GENO 2, BTE 13 WL 85 C090	GENO 2, BTE 13 WL 85 C090	OTICON A/S	-	-	-
-	-	GENO 2, BTE P 13 WL 100 C090	GENO 2, BTE P 13 WL 100 C090	OTICON A/S	-	-	-
-	-	GENO 2, BTE PP 13 WL 105 C090	GENO 2, BTE PP 13 WL 105 C090	OTICON A/S	-	-	-
-	-	OTICON GENIE 2 & GENIE	OTICON GENIE 2 & GENIE	OTICON A/S	-	-	-
MDA/DM/2019/087	DUERR DENTAL SOUTH EAST ASIA SDN BHD	VISTASCAN NANO EASY	DUERR DENTAL	DÜRR DENTAL SE	MALAYSIA INTERNATIONAL DENTAL EXHIBITION AND CONFERENCE (MIDEC 2019) 18TH PENANG DENTAL CONGRESS	KUALA LUMPUR CONVENTION CENTRE (KLCC) HOTEL EQUATORIAL, PENANG	11/7/2019 – 14 /7/2019 28/09/2019 Period of Demo: 02/07/2019 – 30/09/2019
-	-	MYLUNOS POWDER JET HANDPIECE	DUERR DENTAL	DÜRR DENTAL SE	-	-	-
-	-	FD 300 TOP WIPES SURFACE DISINFECTION	DUERR DENTAL	OROCHEMIE GMBH + CO. KG	-	-	-
-	-	FD366 SENSITIVE TOP WIPES	DUERR DENTAL	OROCHEMIE GMBH + CO. KG	-	-	-
-	-	FD 360 CLEANING AND CARE OF VINYL UPHOLSTERY	DUERR DENTAL	OROCHEMIE GMBH + CO. KG	-	-	-
-	-	ID 215 ENZYMATIC INSTRUMENT CLEANER	DUERR DENTAL	OROCHEMIE GMBH + CO. KG	-	-	-
MDA/DM/2019/096	AJ RESEARCH & PHARMA SDN BHD	UNEKOS 200 -INJECTABLE FOR INTRADERMAL IMPLANT	SUNEKOS 200	PROFESSIONAL DIETETICS INTERNATIONAL S.R.L.	5TH MSAM CONFERENCE 2019	HILTON SENTRAL KUALA LUMPUR	21/9/2019 - 22/9/2019 Period of Demo: 15/07/2019 – 13/10/2019
-	-	SUNEKOS 1200 INJECTABLE FOR INTRADERMAL IMPLANT	SUNEKOS 1200	PROFESSIONAL DIETETICS INTERNATIONAL S.R.L.	-	-	-
MDA/DM/2019/099	MEDIK GEN SDN BHD	INFANT RADIANT WARMER	OKM730	OKUMAN MEDIKAL SISTEMLER A.S.	EXHIBITIONS, ASMIC 2019, MEDEX 2019	SHANGRI-LA HOTEL KUALA LUMPUR, MITC	06/09/2019 - 08/09/2019 & 15/10/2019 – 18/10/2019
-	-	BILICARE INTENSIVE PHOTOTHERAPY	OKUMAN	OKUMAN MEDIKAL SISTEMLER A.S.	-	-	-
-	-	LILY SUCTION SYSTEM	CSB-200, CSB-200S, CSB-021	LILY MEDICAL CORPORATION	-	-	-
-	-	AMORPHOUS HYDROGEL	LUOFUCON / HA015	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	EXTRA SILVER ALGINATE DRESSING	LUOFUCON / XA125100	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	SILICONE FOAM DRESSING BORDER	LUOFUCON / FD100100	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	SUPER ABSORBENT DRESSING	LUOFUCON \ SP060900	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	POST-OP DRESSING	LUOFUCON / SC06900 / SC060090	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	ALGINATE DRESSING	LUOFUCON \ AD100100	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	FOAM DRESSING	LUOFUCON / FD100100	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	HYDROGEL DRESSING NON-BORDER	LUOFUCON / HG100100	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	SILICONE GEL SCAR SHEET CLEAR	LUOFUCON / SS060120	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	SILICONE WOUND CONTACT DRESSING	LUOFUCON / SC500700	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
-	-	LIVAC RETRACTION SYSTEM	LIVAC / FG04153 / FG04155	LIVAC PTY LTD	-	-	-
-	-	ALGINATE ROPE 2G	LUOFUCON	HUIZHOU FORYOU MEDICAL DEVICES CO.,LTD.	-	-	-
MDA/DM/2019/101	GLOBALMED SDN BHD	SURGICAL MONITOR	ADVANTECH / PAX-324	1, ALLEY 20, LANE 26, RUEIGUANG ROAD, NEIHU DISTRICT, TAIPEI 114, TAIWAN	ASSOCIATION OF PRIVATE HOSPITALS, MALAYSIA (APHM) INTERNATIONAL HEALTHCARE EXHIBITION 2019	KUALA LUMPUR CONVENTION CENTRE	29/07/2019 - 31/07/2019 Period of Demo: 15/07/2019 – 30/09/2019
MDA/DM/2019/102	PHILIPS MALAYSIA SDN BERHAD	TEMPUS LS AUTOMATED EXTERNAL DEFIBRILLATOR	RDT 00-3010	SCHILLER AG	ANNUAL SCIENTIFIC MEETING ON INTENSIVE CARE & 3RD ASIAN PAEDIATRIC INTENSIVE CARE CONGRESS	SHANG-RI LA HOTEL, 11, JALAN SULTAN ISMAIL, KUALA LUMPUR, 50250 KUALA LUMPUR, WILAYAH PERSEKUTUAN KUALA LUMPUR, MALAYSIA	07/08/2019 – 08/09/2019
-	-	V60 PLUS VENTILATOR	PHILIPS 1137276	RESPIRONICS CALIFORNIA, LLC	-	-	-
-	-	AC611 HIGH FLOW NASAL CANNULA	PHILIPS 1134196, 1134197, 1134198, 1134199, 1134200, 1134201, 1137426	RESPIRONICS, INC.	-	-	-
-	-	HEARTSTART INTREPID MONITOR/DEFIBRILLATOR	PHILIPS 867172	PHILIPS GOLDWAY (SHENZHEN) INDUSTRIAL INC.	-	-	-
-	-	INTELLISPACE CONSOLE CRITICAL CARE	PHILIPS 867065, 867066	PHILIPS MEDICAL SYSTEMS	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
MDA/DM/2019/103	EDWARDS LIFESCIENCES (MALAYSIA) SDN BHD	HEMOSPHERE PRESSURE CABLE	BRAND: HEMOSPHERE / MODEL NO: HEMPSC100	EDWARDS LIFESCIENCES LLC	PRODUCT DEMONSTRATION FOR TRAINING PURPOSE	EDWARDS LIFESCIENCES MALAYSIA OFFICE	4/11/2019 - 8/11/2019
-	-	HEMOSPHERE PRESSURE-OUT CABLE	BRAND: HEMOSPHERE / MODEL NO.:HEMDPT1000	EDWARDS LIFESCIENCES LLC	-	-	-
MDA/DM/2019/104	STRAITS SCIENTIFIC (M) SDN BHD	MULTI-4 CO-OXIMETER CONTROL MULTI PAK	MULTI-4	INSTRUMENT LABORATORY COMPANY	EVALUATION DEMONSTRATION FOR CO-OXIMETER	JABATAN KIMIA MALAYSIA (KOTA KINABALU) JABATAN KIMIA MALAYSIA (JOHOR) JABATAN KIMIA MALAYSIA (PETALING JAYA)	1/8/2019 - 30/10/2019
MDA/DM/2019/110	EASMED SDN BHD	LUMENIS PULSE™ LASER SYSTEMS	LUMENIS	LUMENIS	17TH UROLOGICAL ASSOCIATION OF ASIA CONGRESS (UAA) 2019	KUALA LUMPUR CONVENTION CENTRE (KLCC)	7/8/2019 - 10/8/2019 Period of Demo: 22/07/2019 – 31/08/2019
-	-	VERSACUT™ MORCELLATOR SYSTEM	LUMENIS	LUMENIS	-	-	-
-	-	HOLEP SIMULATOR SYSTEM TYPE B	LUMENIS	LUMENIS	-	-	-
MDA/DM/2019/111	UMMI SURGICAL SDN BHD	CALCULASE III FIBER 230?M REUSABLE	UL007	KARL STORZ SE & CO. KG	17TH UROLOGICAL ASSOCIATION OF ASIA CONGRESS (UAA) 2019 UNIMAS SKULL BASE WORKSHOP ENT WORKSHOP	KUALA LUMPUR CONVENTION CENTRE (KLCC) UNIVERSITY OF MALAYSIA SARAWAK (UNIMAS) UNIVERSITI KUALA LUMPUR ROYAL COLLEGE OF MEDICINE PERAK (UNIKL RCMP)	7/8/2019 - 10/8/2019 13/9/2019 -21/9/2019 2/10/2019 - 8/10/2019
-	-	CALCULASE III FIBER 365 ?M REUSABLE	UL008	KARL STORZ SE & CO. KG	-	-	-
-	-	LUER PORT WITH STOP COCKS	11014L	KARL STORZ SE & CO. KG	-	-	-
-	-	DOUBLE LUER PORT	11014LU	KARL STORZ SE & CO. KG	-	-	-
-	-	CLEANING ADAPTOR FOR WORKING CHANNEL	11014RA	KARL STORZ SE & CO. KG	-	-	-
-	-	SUCTION ELEVATOR, 19 CM	474001	KARL STORZ SE & CO. KG	-	-	-
-	-	FLUORESCIN BLUE FILTER SYSTEM	20100032	KARL STORZ SE & CO. KG	-	-	-
-	-	FLUORESCIN BARRIER FILTER	20100033	KARL STORZ SE & CO. KG	-	-	-
-	-	WIRE CRIMPER, SHORT JAWS, 8 CM	227401K	KARL STORZ SE & CO. KG	-	-	-
-	-	FORCEPS, OVAL, 1.8 MM, STRAIGHT	662221	KARL STORZ SE & CO. KG	-	-	-
-	-	FORCEPS, OVAL, 1.8 MM, RIGHT	662223	KARL STORZ SE & CO. KG	-	-	-
-	-	FORCEPS, OVAL, 1.8 MM, 15 CM,LEFT	662224	KARL STORZ SE & CO. KG	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	FORCEPS, OVAL 1.8 MM, 15 CM, 45°	662227	KARL STORZ SE & CO. KG	-	-	-
-	-	FORCEPS, OVAL, 1.8 MM, 90°	662228	KARL STORZ SE & CO. KG	-	-	-
-	-	BONE PUNCH	649003	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1-MODULE	40810020	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1 ELECTROMAGNETIC MODULE	40820020	KARL STORZ SE & CO. KG	-	-	-
-	-	NAV1 ELECTROMAGNETIC FIELD GENERATOR	40820030	KARL STORZ SE & CO. KG	-	-	-
-	-	MARKING INSTRUMENT, NASAL TIP, 11 CM	488030	KARL STORZ SE & CO. KG	-	-	-
-	-	RUBIN SEPTUM MORCELIZER	488038	KARL STORZ SE & CO. KG	-	-	-
-	-	ALA GUIDING INSTRUMENT FOR 488065 B	488065A	KARL STORZ SE & CO. KG	-	-	-
-	-	FIXATION BLOCK FÜR 488065 A	488065B	KARL STORZ SE & CO. KG	-	-	-
-	-	PROTECTION TUBE, METAL, 6 CM	225150	KARL STORZ SE & CO. KG	-	-	-
-	-	EM PATIENT TRACKER	40820086	KARL STORZ SE & CO. KG	-	-	-
-	-	EM ENDOSCOPE TRACKER, UNIVERSAL	40820150	KARL STORZ SE & CO. KG	-	-	-
-	-	PANEL PC FOR NAV1 PICO	40800020	KARL STORZ SE & CO. KG	-	-	-
-	-	NAVIGATION CAMERA	40800030	KARL STORZ SE & CO. KG	-	-	-
-	-	ELECTRONIC BOX	40800040	KARL STORZ SE & CO. KG	-	-	-
-	-	PATIENT TRACKER II	40800087	KARL STORZ SE & CO. KG	-	-	-
MDA/DM/2019/112	R. E. ROGERS (MALAYSIA) SDN BHD	MEDICAL EXAMINATION BED/ CHAIR	AMC 2510 ONYX PEWTER	FORME MEDICAL THAILAND	APHM INTERNATIONAL HEALTHCARE CONFERENCE & EXHIBITION 2019	KUALA LUMPUR CONVENTION CENTRE	29/07/2019 - 31/07/2019 Period of Demo : 28/07/2019 – 26/10/2019
-	-	MEDICAL EXAMINATION BED/ CHAIR	AMC 2520 TANZANITE WINDSOR	FORME MEDICAL THAILAND	-	-	-
MDA/DM/2019/116	INTERSCIENCE SDN BHD	ALINITY M HIV-1 AMP KIT	ALINITY M HIV-1	ABBOTT MOLECULAR INC	PRESENTATION / EXPLANATION	HOSPITAL SG. BULOH, SUNGAI BULOH, SELANGOR DARUL EHSAN	13/8/2019 - 11/11/2019
-	-	ALINITY M HIV-1 CAL KIT	ALINITY M HIV-1	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HIV-1 CTRL KIT	ALINITY M HIV-1	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HIV-1 APPLICATION SPECIFICATION FILE	ALINITY M HIV-1	ABBOTT MOLECULAR INC	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	ALINITY M HCV AMP KIT	ALINITY M HCV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HCV CAL KIT	ALINITY M HCV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HCV CTRL KIT	ALINITY M HCV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HCV APPLICATION SPECIFICATION FILE	ALINITY M HCV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HBV AMP KIT	ALINITY M HBV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HBV CAL KIT	ALINITY M HBV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HBV CTRL KIT	ALINITY M HBV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M HBV APPLICATION SPECIFICATION FILE	ALINITY M HBV	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M SYSTEM	ALINITY M SYSTEM	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M PIPETTE TIPS, 50 ?L	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M PIPETTE TIPS, 1000 ?L	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M INTEGRATED REACTION UNITS (IRU)	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M IRU WASTE CONTAINER	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M WASTE BOX	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M ASSAY TRAY CARRIER	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M UNIVERSAL SAMPLE RACK	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M SAMPLE RACK HOLDER	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M WASTE BOTTLE	ACCESSORIES	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M TRANSPORT TUBE	ALINITY M TRANSPORT TUBE	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M SAMPLE PREP KIT 2	ALINITY M SAMPLE PREP KIT 2	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M LYSIS SOLUTION	ALINITY M SYSTEM SOLUTION	ABBOTT MOLECULAR INC	-	-	-
-	-	ALINITY M DILUENT SOLUTION	ALINITY M SYSTEM SOLUTION	ABBOTT MOLECULAR INC	-	-	-

NOTIFICATION OF EXEMPTION – LIST OF ACKNOWLEDGEMENT ON NOTIFICATION FOR DEMONSTRATION

UPDATED ON 23/08/2019

NOTIFICATION ID	COMPANY	DEVICE NAME	BRAND	MANUFACTURER	TYPE OF EVENT	DEMO LOCATION	DEMO DATE
-	-	ALINITY M VAPOR BARRIER SOLUTION	ALINITY M SYSTEM SOLUTION	ABBOTT MOLECULAR INC	-	-	-
MDA/DM/2019/118	PHILIPS MALAYSIA SDN BERHAD	TRILOGY EVO	PHILIPS RESPIRONICS IN2100X15B	RESPIRONICS, INC.	ANNUAL SCIENTIFIC MEETING ON INTENSIVE CARE & 3RD ASIAN PAEDIATRIC INTENSIVE CARE CONGRESS HOME VENTILATION COURSE	SHANG-RI LA HOTEL, 11, JALAN SULTAN ISMAIL, KUALA LUMPUR. THE CUBE, LEVEL 4, FACULTY OF MEDICINE, UNIVERSITY OF MALAYA	5/9/2019 - 8/9/2019 17/11/2019 - 23/11/2019
MDA/DM/2019/120	INTERSCIENCE SDN BHD	VYSIS MET SPECTRUMRED FISH PROBE KIT	ABBOTT	ABBOTT MOLECULAR INC	PRESENTATION / EXPLANATION	PANTAI PREMIER PATHOLOGY SDN BHD JALAN BUKIT PANTAI	19/8/2019 - 23/8/2019 Period of Demo: 30/07/2019 – 28/10/2019
MDA/DM/2019/122	BMS DIAGNOSTICS (M) SDN BHD	SST-R KITS (DRAWERS, SLIDES, MOUNTING KIT, ANTENNAS, CALCULATOR)	BIOLOGID/ SST-R 225	BIOLOGID	DEMONSTRATION FOR BIOLOGID SST-R KITS	TRANSFUSION MEDICINE DEPARTMENT, UNIVERSITI MALAYA MEDICAL CENTRE	17/9/2019 - 16/12/2019
-	-	SST-R KITS (DRAWERS, SLIDES, MOUNTING KIT, ANTENNAS, CALCULATOR)	BIOLOGID/ SST-R 112	BIOLOGID	-	-	-
MDA/DM/2019/123	JETPHARMA SDN BHD	SINUSULTRA ULTRASOUND	ULTRAMAX	ENTLAB	DEMONSTRATION	1HUKM 2HUSM 3THOMSON HOSP 4RSD SUBANG JAYA 5PANTAI HOSP KL 6KPJ PUTERI HOSP 7KEMPAS MC 8HOSP TAIPING 9HRPB IPOH 10GLENEAGLES HOSP KK 11HOSP UMUM SARAWAK 12ASSUNTA HOSP 13AVISENA SPEC HOSP 14UMMC 15TIMBERLAND MC 16LOH GUAN LYE HOSP 17LAM WAH EE HOSP	As per list attachment Period of Demo : 15/09/2019 – 14/12/2019
MDA/DM/2019/120	SUNSTAR SINGAPORE PTE. LTD. (REGIONAL OFFICE)	BUTLER GRINDCARE	BUTLER	SUNSTAR EUROPE S.A.	13TH ASIAN PACIFIC SOCIETY OF PERIODONTOLOGY (EXHIBITION) 13TH ASIAN PACIFIC SOCIETY OF PERIODONTOLOGY MEETING (EXHIBITION)	ROYALE CHULAN KUALA LUMPUR	28/9/2019 -29/9/2019
-	-	BUTLER GRINDCARE GELPAD	BUTLER	SUNSTAR EUROPE S.A.	-	-	-

END OF LIST