



No.F.4-4/2023-MD (M-56)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 13th March, 2023

Subject:- **ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT – DEFERRED CASES (SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF)**

The applications of following applicants were placed before Medical Device Board (MDB) in its 56th meeting held on 2nd March, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
I	II	III	IV	V
1.	M/s MHK Enterprises, Jalal heights, Flat No.201, Plot No.4 St, Al-Hilal, Co-Operative Housing Society, Karachi. 1030 Evaluator AD-VIII	Zybio Inc. Floor 1 to floor 5, Building 30, No 6, of Taikang Road Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, China	HEMATOLOGY ANALYZER Z3 HEMATOLOGY ANALYZER Class A Service life 7 years	Deferred for provision of valid original embassy attested FSC in the country of origin and of any reference country as given under rule 67 of the MDR 2017. Provide CE marking certificate including FQA.
2.	M/s MHK Enterprises, Jalal heights, Flat No.201, Plot No.4 St, Al-Hilal, Co-Operative	Zybio Inc. Floor 1 to floor 5, Building 30, No 6, of Taikang Road Block C of Jianqiao Industrial Park, Dadukou	LB LYSE FOR HEMATOLOGY ANALYZER Z5 Class A Shelf life 2 years	Deferred for provision of valid original embassy attested FSC in the country of origin or any reference country as given under rule 67 of the MDR 2017. Provide CE marking certificate including.


	Housing Society, Karachi. 1031 Evaluator AD- VIII	District,400082 Chongqing, China		
3.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Roche Dossier # 0150	Legal Manufacturer: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany. Manufacturing Site: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany. Free Sale Certificate Baden-Wurttember Certificate of Marketability Date of Issue: 15- 03-2017 New FSCs of Germany issuance date 11.07.22 And 11.07.2022 Soft checked	IVD System of Cobas b221 Analyzer with accessories Class: A Fees: 5,000/- 1. Cobas b221 2 Roche OMNI S2 System Size: 1 unit Code: 03337111001 Shelf Life: N/A 2. Cobas b221 4 Roche OMNI S4 System Size: 1 unit Code: 03337138001 Shelf Life: N/A 3. Cobas b221 6 Roche OMNI S6 System Size: 1 unit Code: 03337154001 Shelf Life: N/A 4. AUTO QC MODUL cobas b 221=Roche OMNI S Size: 1 unit Code: 03313522001 Shelf Life: N/A 5. THB Cuvette Packed Size: 1 unit Code: 03086879001 Shelf Life: N/A (Non-IVD)	Deferred for clarification and submission of the following documents: 1. The firm has submitted three systems in single application Clarify. 1.Cobas b221 2 Roche OMNI S2 System 03337111001 2. Cobas b221 4 Roche OMNI S4 System Code: 03337138001 3. Cobas b221 6 Roche OMNI S6 System Code: 03337154001 2. The brand name on FSC is different then on form6A need clarification or revise Form-6 A (AUTO QC MODUL cobas b 221=Roche OMNI S) 3. The firm has not provided FSC of the products at serial no 5 and 06 and has stated that they are non IVD. The firm may apply separately for these products.

			6. SENSOR CONTACT (SCON) Size: 1 unit Code: 03260909184 Shelf Life: N/A (Non-IVD)	
4.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Roche Dossier # 0159	Legal Manufacturer: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany. Manufacturing Site: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany. Free Sale Certificate Baden-Wurttemberg Certificate of Marketability Date of Issue: 15-03-2017 Valid FSC submitted 11-07-2022	U411 Urine Analyzer Class: A Fees: 5000/- 1. Cobas u 411 Analyzer Code: 04906969001 Size: 1 Unit Shelf Life: N/A 2. Reference Pad Code: 11907131001 Size: One pack of 5 rolls Shelf Life: N/A 3. Test Strip Tray, Type C Code: 03666735001 Size: One pack Shelf Life: N/A 4. URISYS Thermo-printer paper Code: 04352483001 Size: One pack of 5 rolls Shelf Life: N/A	Deferred for clarification or provision of the embassy attested original and valid FSC for. Reference Pad Code: 11907131001 3. Test Strip Tray, Type C Code: 03666735001 4. URISYS Thermo-printer paper Code: 04352483001
5.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.	Legal Manufacturer: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim,	Cobas e411 Analyzer with accessories Class: A Fees: 5000/- 1. cobas e 411 Rack Analyzer Size: One unit	Deferred for provision of following: • Provide clarification or Original and Valid embassy attested FSC for products at serial no 09,10,11.

<p>(ELI-00009)</p> <p>Roche Dossier # 0128</p>	<p>Germany.</p> <p>Manufacturing Site: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany.</p> <p>Free Sale Certificate Baden-Wurttemberg Certificate of Marketability Date of Issue: 15-03-2017 30-11-2022 11-07-2022 Valid FSC submitted</p>	<p>Code: 04775201001 Shelf Life: N/A</p> <p>2. CleanCell Size: 6 x 380 ml Code: 11662970122 Shelf Life: 24 months</p> <p>3. ProCell Size: 6 x 380 ml Code: 11662988122 Shelf Life: 24 months</p> <p>4. ASSAY CUP Size: 60 x 60 Cups Code: 11706802001 Shelf Life: N/A</p> <p>5. ASSAY TIP Size: 30 x 120 Tips Code: 11706799001 Shelf Life: N/A</p> <p>6. CLEAN LINER Size: One Box Code: 11800507001 Shelf Life: N/A</p> <p>7. Elecsys SysWash Size: 500 ml Code: 11930346122 Shelf Life: 8 months</p> <p>8. CALSET VIALS Size: 500 ml Code: 11776576322 Shelf Life: N/A</p> <p>9. ADAPTER SYS CLEAN KU FBL Size: One Box Code: 11933159001 Shelf Life: N/A</p> <p>10. SAP Tests</p>	<p>• Provide Original and valid embassy attested FSC of the Products at serial no 1,2,3,4,5,6,7,8, 12,13</p>
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			Size: One Box Code: 11820435122 Shelf Life: N/A 11. CAP TWIST Size: One Box Code: 11812041001 Shelf Life: N/A 12. Sample Cup Micro 13/16 Size: 450 Cups Code: 05085713001 Shelf Life: N/A 13. sample cup (Cobas) Size: 5000 Cups Code: 10394246001 Shelf Life: N/A	
6.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Roche dossier# 0167	Manufacturer: Roche Molecular Diagnostics Inc., 1080US Highway 202 South Branchburg, NJ 08876,USA. Manufacturing Site: Roche Diagnostics International Ltd Forrenstrasse 2 6343 Rotkreuz Switzerland Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA Baden- Wurrtemberg Certificate of Marketability	Cobas z 480 Analytical unit Class: A • Code: 05200881001 Cobas z 480 Analyzer Size: 1 Unit Shelf life: NA • Code: 05235863190 05235871190 Cobas 4800 System Wash Buffer Kit Size: 240 Tests, 960 Tests Shelf life: 18 months • Code: 05340403001 Goose Neck Display Size: 1 Unit	Deferred for clarification and submission of the following documents: - Provide clarification or embassy attested valid and original FSC of the product mentioned at serial no 3,4,5,6,7, 3.05340403001 Goose Neck Display 4. Code: 06466273190 Set Cobas 4800 UL Series System IOQ LOU 5.Code: 08153299001 FortiGate - 50E 6.Code: 04691989001 Solid waste bags


		Date of issuance: 23-03-2021	Shelf life: NA <ul style="list-style-type: none"> Code: 06466273190 Set Cobas 4800 UL Series System IOQ LOU Size: 1 Unit Shelf life: NA Code: 08153299001 FortiGate - 50E Size: 1 Unit Shelf life: NA Code: 04691989001 Solid waste bags Size: set of 50 Shelf life: NA Code: 05530873001 Solid waste bags Size: set of 25 Shelf life: NA Code: 05235847190 Kit Cobas 4800 SYS CTL DIL Size: 10 x 4.3ml Shelf life: 18 months Code: 05235839190 Kit Cobas 4800 Sys LIQ CYT Prep 960t IVD Size: 960 Test Shelf life: 18 months Code: 05235812190 	7.Code: 05530873001 Solid waste bags The firm has applied many kits in one application need clarification for the following products 05235847190 Kit Cobas 4800 SYS CTL DIL 10 SETS IVD Shelf life: 18 months Code: 05235839190 Kit Cobas 4800 Sys LIQ CYT Prep 960t IVD Shelf life: 18 months Stability studies not provided.
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			<p>Kit Cobas 4800 Sys LIQ CYT Prep 240t IVD Size: 240 Test Shelf life: 18 months</p> <p>• Code: 05235782190 Cobas 4800 System Sample Preparation Kit, 240 Tests Size: 240 Test Shelf life: 18 months</p> <p>• Code: 05235804190 Cobas 4800 System Sample Preparation Kit, Size: 960 Tests Shelf life: 18 months</p>	
7.	<p>Roche Pakistan Limited.</p> <p>1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009) 2</p> <p>Roche dossier# 0189</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics Automation Solutions GmbH Bernhardslaicher Weg 10 71686 Remseck, Germany OR Roche Diagnostics Automation Solutions GmbH, Abert-Ruprecht-Strasse 2 71636 Ludwigsburg, Germany</p>	<p>Cobas p 512 pre-analytical unit</p> <p>Class: A Fee submitted: Rs.5000 Cobas p 512 pre-analytical unit</p> <p>Cobas p 512 pre-analytical unit Size – One Unit Code – 07563124001 Shelf life – N/A</p> <p>• Cobas p 471 centrifuge unit Size – One Unit Code – 07563787001 Shelf life – N/A</p> <p>3. Bulk Loader for Cobas p 471 Size – One Unit Code – 07084285001</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Original and embassy attested FSC in the country of origin as the provided one is copy. • The firm has applied two systems in one application, justify under MDR ,2017 otherwise apply separately for Bulk Loader Module for p512/612 

		Free Sale certificate: Baden-Wurttember Certificate of Marketability Date of issuance: 03-06-2021	Shelf life – N/A 4. Bulk Loader Module for p512/612 Size – One Unit Code – 07135645001 Shelf life – N/A	
8.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Roche dossier# 0182	Manufacturer: Hamilton Bonaduz, AG CH-7402, Bonaduz Switzerland Manufacturing Site: Hamilton Bonaduz, AG CH-7402, Bonaduz Switzerland Free Sale certificate: Swissmedic Free Sale certificate Date of issuance: 08-03-2021	TIP CORE (HAMILTON) Class: A Fee Submitted: Rs. 5000 Shelf life: NA 1)Code: 07345607001 CO-RE Tips 300ul Pack size: 12 sets of 5 x 96 Tips 2)Code: 04639642001 CORE Tip 1000ul Pack size: 3840 Tips 3)Code: 07102127001 CORE TIPS Filter, 50ul Pack size: 12 sets of 5 x 96 Tips	Deferred for provision of the following 1. The firm has provided copy of FSC. therefore, submit embassy attested valid FSC. 2. The brand name CORE Tip (04639642001) on FORM-6 is different then present on FSC 3. provide clarification. Provide Notarised and valid LOA, ISO 13485 and FQA since only copies are provided.
9.	Roche Pakistan Limited, 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site:	Cobas 6500 Installation Kit for LAS Class: A Fee submitted: Rs. 5000	Deferred for provision of following: • Original and embassy attested FSC in the country of origin only undertaking provided for providing the embassy attested FSC

	Roche dossier # 0198	77 Elektronika Műszeripari Kft Fehérvári út 98. 1116 Budapest Hungary	Code: 07438451001 Cobas 6500 Installation Kit for LAS Pack size: One unit Shelf life: NA	<ul style="list-style-type: none"> • Provide notarized and valid ISO 13485 certificate for Hungary site
10.	Roche Pakistan Limited, 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Roche dossier # 0126	Manufacturer: Ventana Medical Systems Inc. 1910 E. Innovative Park Drive, Tucson, Arizona, USA 85755. Tel: +(520) 887-2155, Fax: +(520)-229-4207 Website: www.ventana.com Manufacturing Site: Ventana Medical Systems Inc. 1910 E. Innovative Park Drive, Tucson, Arizona, USA 85755. U.S. Food & Drug Administration, USA. Certificate to Foreign Government (CFG) Certificate No 6846-3-2019	BenchMark XT System with accessories Class: A Fee submitted: Rs. 5000 Shelf Life: NA <ul style="list-style-type: none"> • Roche # 5265231001 Ventana # 750-700 Name: BENCHMARK XT System Pack Size: One Unit • Roche # 5342724001 Ventana # 750-602 Name: Ventana Benchmark Ultra Computer System Pack Size: One Unit • Roche # 5256143001 Ventana # Nil Name: Kit, Accessory 1, XT Pack Size: One Unit • Roche # 5256577001 Ventana # Nil Name: Kit, Accessory 2, XT 	Deferred for the following documents 1. Original and embassy attested FSC in the country of origin not provided only copy provided and has provided an undertaking provided for providing the embassy attested FSC. 2. the firm may apply separately or shall provide embassy attested valid FSC of the products mentioned at serial no 02,3,4,5,6,7,8,9.

			<p>Pack Size: One Unit</p> <ul style="list-style-type: none"> • Roche # 6376517001 Ventana # Nil Name: Bottle Ship Kit, BMK XT/LT, Raised ACC Pack Size: One Unit • Roche # 5250986001 Ventana # Nil Name: ASSY, WASTE CONTAINER AND CART Pack Size: One Unit 7.Roche # 5244676001 Ventana # Nil Name: BOTTLE, 20 LITER GRADUATED Pack Size: One Unit 8.Roche # 5250862001 Ventana # Nil Name: ASSY, EBAR PRINTER Pack Size: One Unit 9.Roche # 5247829001 Ventana # Nil Name: Label, Blank, Flap, 540 Roll Pack Size: one pack of 540 PC 	
11.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi.	Medtronic Minimed 18000 Devonshire St Northridge, CA USA Manufacturing Site SMC COSTA RICA	Minimed Quick-serter MMT-305QS,MMT-305PS Class: A Shelf Life: 1 Year Service Life Fee: 5000 Challan No. 2023381	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Provide Original and embassy attested valid FSC of USA since expired FSC of US was submitted. • Valid and notarized ISO 13485.

	(ELI-00273) [543-6A]	DIV.S.R.L,COSTA RICA FSC: EXPIRED ORIGINAL US FDA PROVIDED Valid Till: 26-4- 2020		• Service life certificate not provided
12.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)	<p>Manufacturer: Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany. Tel: + 49/621-759-0 https://www.roche.com</p> <p>Manufacturing Plant: Sr. 1 Roche Diagnostics International Ltd Forrenstrasse 2, 6343 Rotkreuz, Switzerland.</p> <p>Manufacturing Plant: Sr. 2 & 3. Roche Diagnostics GmbH, Nonnenwald 2, 82377 Penzberg, Germany.</p> <p>Manufacturing Plant: Sr. 4,5 & 6. Greiner Bio-One GmbH Bad Haller Str. 32, 4550 Kremsmunster Austria.</p> <p>Manufacturing Plant: Sr. 7.</p>	<p>MagNA Pure 24 System</p> <p>1)Products Name: MagNA Pure 24 Instrument Code: 07290519001 Size: One Unit Class: Class A. CE-IVD Shelf Life: N/A</p> <p>2)Products Name: MagNA Pure 24 Total NA Isolation Kit Code: 07658036001 Size: 96 Isolations Class: Class A. CE-IVD Shelf Life: 18 months</p> <p>3)Products Name: MagNA Pure 24 MGP Set Code: 07806361001 Size: 12 Tubes Class: Class A.</p>	<p>Deferred for the provision of the following:</p> <p>1. The manufacturing sites mentioned on Form-6A is no aligned with FSC . clarification required.</p> <p>2. The firm has not provided notarized ISO 13485 certificate s of all the manufacturing sites. therefore, provide notarized ISO 13485 certificate of all the sites.</p> <p>3. The firm has not provided FSC of the products mentioned at serial no 19,20,21,22,23,24,25,26,27 clarify or provide embassy attested FSC of the products.</p> <p>4. Justify Isolation kit being part the system</p> 

	<p>Hamilton Bonaduz AG Via Crusch 8 7402 Bonaduz, Switzerland.</p> <p>Manufacturing Plant: Sr. 8,12 & 13. Martignoni AG Dorfmatweg 5, 3110 Munsingen, Switzerland</p> <p>Manufacturing Plant: Sr. 9,10,11,16,17&18 Novoplast Hungaria Kft Csurgoi u 34, 8725 Iharosbereny. Hungary.</p> <p>Manufacturing Plant: Sr. 14 Rau AG Solistrasse 60, 8180 Buelach, Schweiz.</p> <p>Manufacturing Plant: Sr. 15 EuropTec Kft 8900 Zalaegerszeg, Hock J. 96/A Hungary.</p> <p>Free Sale Certificate: Baden-Wuerttember Certificate of Marketability</p> <p>Date of issuance: 16-04-2021</p>	<p>CE-IVD. Shelf Life: 18 months</p> <p>4)Products Name: MagNA Pure 24 Processing Cartridge Code: 07345577001 Size: 24 Cartridges Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>5)Products Name: MagNA Pure 24 Tip Park - Piercing Tool Code: 07345585001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>6)Products Name: MagNA Pure 24 Piercing Tool Code: 07534205001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>7)Products Name: MagNA Pure Tip 1000 µl Code:</p>	
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			06241620001 Size: One Box of 3840 Tips Class: Class A. CE-IVD. Shelf Life: N/A 8)Products Name: MagNA Pure 24 Post Elution Adapter Code: 07931204001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A 9)Products Name: MagNA Pure Reagent Rack Code: 07930836001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A 10)Products Name: MagNA Pure24 Processing Station Adapter Code: 07931212001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A	
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			11)Products Name: MagNA Pure 24 Liquid Waste Insert Code: 07931182001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A	
			12)Products Name: MagNA Pure24 Output Adapter 9 mm Code: 07931140001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A	
			13)Products Name: MagNA Pure 24 Output Adapter 18 mm Code: 07931131001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A	
			14)Products Name: MagNA Pure 24 Down Holder Frame Code: 07931158001 Size: One Unit Class: Class A. CE-IVD.	


			<p>15)Products Name: MagNA Pure 24 Reagent Tip Park Code: 07931166001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>16)Products Name: MagNA Pure 24 Tip Waste Container Code: 07930828001 Size:One Unit Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>17)Products Name: MagNA Pure 24 Sample Rack MP24 Code: 07930852001 Size: One Unit Class: Class A. CE-IVD. Shelf Life: N/A</p> <p>18)Products Name: MagNA Pure 24 Sample Rack 24x 2ml Code: 07931123001 Size: One Unit Class: Class A. CE-IVD.</p>	
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			Shelf Life: N/A 19)Products Name: Empty Tip Tray 96 with Barcode Label Code: 07927380001 Size: One Unit Class: N/A Non-IVD Shelf Life: N/A 20)Products Name: Lamp UVC 15W/24VDC Code: 28127328001 Size: One Unit Class: N/A Non-IVD Shelf Life: N/A 21)Products Name: Handheld Scanner IDM240-1S 2D Code: 07107129001 Size: One Unit Class: N/A Non-IVD Shelf Life: N/A 22)Products Name: Cable DA-BCR CAB- 426E2 2m straight USB-A Code: 07947453001 Size:	
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			<p>One Unit</p> <p>Class: N/A Non-IVD</p> <p>Shelf Life: N/A</p> <p>23)Products Name: MagNA Pure Sealing Foil</p> <p>Code: 06241638001</p> <p>Size: One Box of 100 foils</p> <p>Class: N/A Non-IVD</p> <p>Shelf Life: N/A</p> <p>24)Products Name: FrameStrip ® with flat caps low profile</p> <p>Code: 07345593001</p> <p>Size: One Box of 120 Pcs</p> <p>Class: N/A Non-IVD</p> <p>Shelf Life: N/A</p> <p>25)Products Name: FrameStrip 9® with flat caps high profile</p> <p>Code: 07652275001</p> <p>Size: One Box of 120 Pcs:</p> <p>Class N/A Non-IVD</p> <p>Shelf Life: N/A</p> <p>26)Products Name:</p>	
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			<p>MagNA Pure Tube (2mL) Code: 07857551001 Size: One Box of 350 Pcs Class: N/A Non-IVD Shelf Life: N/A</p> <p>27)Products Name: MAGNA PURE TIP WASTE TRAY Code: 08185492001 Size: One Unit Class: N/A Non-IVD Shelf Life: N/A</p>	
13.	<p>Roche Pakistan Limited.</p> <p>1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009)</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site:</p>	<p>Cobas p 612 pre-analytical system</p> <ul style="list-style-type: none"> • Cobas p 612 pre-analytical system Size – One Unit Code – 07563116001 Shelf life – N/A 1. Cobas p 671 centrifuge unit Size – One Unit Code – 07563795001 Shelf life – N/A 1. Bulk Loader for centrifuge units Cobas p 671 Size – One Unit 	<p>Deferred for submission of the following:</p> <p>1.The Brand names are not aligned with the FSC, like product mentioned at serial no 10,11 and 22. Revise form7A accordingly.</p> <p>2. Submit embassy attested original and valid FSC in the country of origin.</p> 

			<p>Code – 08436223001 Shelf life – N/A</p> <p>1. Tips 1000 µl</p> <p>Size – 9600 Tips (50 x 192) Code – 11901761001 Shelf life – N/A</p> <p>1. Tips 1000 µl non-conductive f. RSD800A</p> <p>Size – 9600 Tips (50 x 192) Code – 04976274001 Shelf life – N/A</p> <p>1. Tips 1000 µl non-conductive pipette tip with filter</p> <p>Size – 9600 Tips (50 x 192) Code – 08176337001 Shelf life – N/A</p> <p>1. Output Unit</p> <p>Size – One Unit Code – 07667574001 Shelf life – N/A</p> <p>1. Add on Buffer Unit</p> <p>Size – One Unit Code – 07667680001 Shelf life – N/A</p> <p>1. Power Supply Unit</p> <p>Size – One Unit</p>	
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			<p>Code – 06770584001 Shelf life – N/A</p> <p>1. Cobas 8000 Connection Unit</p> <p>Size – One Unit Code – 06924484001 Shelf life – N/A</p> <p>1. CCM Bidirectional Interface</p> <p>Size – One Unit Code – 07276001001 Shelf life – N/A</p> <p>1. Cobas 6000 Connection unit</p> <p>Size – One Unit Code – 06770517001 Shelf life – N/A</p> <p>1. HST Connection unit</p> <p>Size – One Unit Code – 06924514001 Shelf life – N/A</p> <p>1. Conveyer 1 unit (0.5m)</p> <p>Size – One Unit Code – 06770568001 Shelf life – N/A</p> <p>1. Conveyer 2 unit (1m)</p> <p>Size – One Unit</p>	
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			<p>Code – 06770576001 Shelf life – N/A</p> <p>1. Conveyer 3 unit (0.31m)</p> <p>Size – One Unit Code – 08302430001 Shelf life – N/A</p> <p>1. Conveyer 4 unit (0.69m)</p> <p>Size – One Unit Code – 08302448001 Shelf life – N/A</p> <p>1. Linear Buffer unit</p> <p>Size – One Unit Code – 08108943001 Shelf life – N/A</p> <p>1. Turn unit</p> <p>Size – One Unit Code – 06770592001 Shelf life – N/A</p> <p>1. CCM Cobas c 513 Connection unit</p> <p>Size – One Unit Code – 08770263001 Shelf life – N/A</p> <p>1. Modular Connection unit</p> <p>Size – One Unit Code – 06770550001 Shelf life – N/A</p>	
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			<p>1. CCM Backend Connection unit</p> <p>Size – One Unit Code – 08858306001 Shelf life – N/A</p> <p>1. CCM Backend Modification kit (BMK)</p> <p>Size – One Unit Code – 09003371001 Shelf life – N/A</p> <p>1. CCM Backend Connection unit (BCU)</p> <p>Size – One Unit Code – 08858314001 Shelf life – N/A</p>	
14.	<p>Roche Pakistan Limited.</p> <p>1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009) 1</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: 05060281001:Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany 05888760001:Celestica Technology Co.,Ltd. No. 448, Suhong Middle Road; Suzhou Industrial</p>	<p>Accu-Chek Inform II</p> <p>Class: A</p> <p>Fee submitted: Rs.5000</p> <p>1)Code: 05060281001</p> <p>Accu-Chek Inform II Accessory Box Kit Pack size: One Unit Shelf life: NA</p> <p>2)Code: 05888760001 Base Unit Hub Pack size: One Unit, Shelf life: NA</p>	<p>Deferred for submission of the following :</p> <p>1. submit original valid and embassy attested FSC of the applied products. since expired copies provided only.</p> <p>2. Two kits applied in one application clarify or apply separately.</p> <p>3. Submit valid and notarized ISO 13485 certificate of all manufacturing sites.</p>

		<p>Park; Suzhou, Jiangsu, 215021; China</p> <p>07671717190:Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>05060303018:Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>04884671001: Konrad-Zuse-Strasse 19-21; 36251 Bad Hersfeld; Germany</p> <p>Asteelflash Bad Hersfeld GmbH</p> <p>08376824190:Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Free Sale certificate: Baden-Wurttemberg Certificate of Marketability</p> <p>Date of issuance: 15-03-2017</p>	<p>3)Code: 07671717190 Accu-Chek Inform II Base Unit Kit Pack size: One Unit</p> <p>4)Code: 05060303018 Accu-Chek Inform II Meter Kit + RF Pack size: One Unit</p> <p>5)Code: 04884671001 Code Key Reader NGBG Pack size: One Unit</p> <p>6)Code: 08376824190 Base Unit Light Pack size: One Unit</p> <p>7)Code: 04805666001 Handheld Power Pack size: One Unit</p>	
15.	<p>Roche Pakistan Limited.</p> <p>1st Floor, 37-B, Block 6,</p>	<p>Manufacturer: Ventana Medical Systems Inc.</p>	<p>IVD BenchMark Special Stains</p> <p>Products Name:</p>	<p>Deferred for submission of the following documents:</p> 

<p>P.E.C.H.S, Karachi. (ELI-00009)</p>	<p>1910 E. Innovative Park Drive, Tucson, Arizona, USA 85755. Tel: +(520) 887- 2155 Fax: +(520)-229- 4207 Website:www.venta na.com Manufacturing Site: Ventana Medical Systems Inc. 1910 E. Innovative Park Drive, Tucson, Arizona, USA 85755. Tel: +(520) 887- 2155.Fax: +(520)- 229-4207 Website:www.venta na.com</p>	<p>Benchmark Special Stains Waste Module 230V Cat #:06468365001 Size: - Class: Class A. Shelf Life: - Products Name: BenchMark Special Stains System Cat #:06468373001 Size: - Class: Class A. Shelf Life: N/A Products Name: Benchmark Special Stains Liquid Coverslip Cat #:06523072001 Size: 2 L Class: Class A. Shelf Life: 12 months Products Name: Benchmark Special Stains Deparaffinization Solution (10X) Cat #:06523102001 Size: 2 L Class: Class A. Shelf Life: 24 months Products Name: Special Stains Clean Plus Cat #: 06649327001</p>	<p>Provide valid and embassy attested original FSC for all applied products only copy provided. The firm need to clarify as system and kits both are applied in one application (Bench Mark Special Stains System, Accessory Kit BMK Special Stains) Provide Stability studies of all the products claimed shelf life</p>
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			Size: 27 ml Class: Class A. Shelf Life: 24 months Products Name: Reagent Tray, BMK Special Stains Cat #: 06563716001 Size: - Class: Class A. Shelf Life: - Products Name: Accessory Kit BMK Special Stains Cat #: 06564909001 Size: - Class: Class A. Shelf Life: - Products Name: ISH Protease 3 Cat #: 05273331001 Size: - Shelf Life: 18 months Products Name: Reaction Buffer Concentrate (10X) Cat #: 05353955001 Size: 2 L Class: Class A. Shelf Life: 24 months Products Name: Cell Conditioning Solution (CC1) Cat #: 05279801001 Size: 2 L	
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			Class: Class A. Shelf Life: 24 months Products Name: LCS (Predilute) Cat #: 05264839001 Size: 2 L Class: Class A. Shelf Life: 18 months Products Name: ULTRA LCS (Predilute) Cat #: 05424534001 Size: 2 L Class: Class A. Shelf Life: 18 months	
16.	M/s Blazon Diagnostic, Blazon House No. 45,46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 3510-P AD-III	Legal Manufacturer: M/s Mexpo International, Inc.2828 Faber Street, Union City, CA 94587-1204, USA FSC: USA Valid till: 10/04/2020	Discovery 2020 Latex Surgical Gloves (Latex Surgical Glove (Sterile, Powdered) Class-B Shelf Life: Not given Codes & Sizes: As per FSC	Deferred for provision of following:- <ul style="list-style-type: none"> Differential fee of Rs-20,000/- The firm submitted in Class-B but fee submitted is only 5,000/- Credentials of manufacturer's abroad, duly notarized. Original and notarized LOA. Original, valid and attested FSC of US FDA, the submitted document are copies and without notarization and attestation. Updated and notarized ISO 13485 and FQA certificates. Shelf life studies. MRP of the device.

				<ul style="list-style-type: none"> • Grouping of the applied device and codes/ sizes are not mentioned on Form-7A.
17.	M/s Blazon Diagnostic, Blazon House No. 45,46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 704-P AD-III	Legal Manufacturer: M/s Centrion Co., Ltd , Bucheon Techno Park Ssangyong 3 cha 397, Seokecheon-ro, Ojeong-gu, Bucheon-si, Republic of Korea FSC Not Found	Centrion Biocanvas LF Fermentor Controller/Bioreactor (Fermentor Controller/Bioreactor) Class-A Shelf Life: N/A	Deferred for provision of following:- The firm shall submit embassy attested and valid FSC in the country of origin <ul style="list-style-type: none"> • Grouping of the applied device is not mentioned. • Updated and notarized ISO 13485 and FQA certificates are missing. • Essential Principle checklist. • Labels of the applied device. • Declaration of conformity provided does not mention the Class of medical device.
18.	M/s Blazon Diagnostic, Blazon House No. 45,46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 705-P AD-III	Legal Manufacturer: M/s Shanghai Huifeng Medical Instrument Co., Ltd. Building No. 2, No. 885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China FSC: Not Found	HFMED Operating Table (Operating Table) Class-A Service Life: 15 years Model: HFEOT99S	Deferred for provision of following: <ul style="list-style-type: none"> • The firm shall submit embassy attested and valid FSC in the country of origin. • Essential Principle of safety and performance checklist. • Labels. • FQA certificate.
19.	M/s Blazon Diagnostic, Blazon House No. 45,46, 47, Cricket Stadium, double road, Rawalpindi.	Legal Manufacturer: M/s Mexpo International Inc. 2828 Faber Street, Union City, CA 94587, 1204, USA	Discovery 2020 (Latex-Exam Gloves (Non-Sterile, Powdered) Class-A	Deferred for provision of following: <ul style="list-style-type: none"> • Original, valid and attested FSC of US FDA, the submitted document are copies and without notarization and attestation.

	ELI: 00307 706-P AD-III	FSC: USA Valid till: 10/04/2020	Shelf Life: 05 years	<ul style="list-style-type: none"> Updated and notarized ISO 13485 and FQA certificates. MRP of the device. Grouping of the applied device and codes/ sizes are not mentioned on Form-7A.
20.	M/s Blazon Diagnostic, Blazon House No. 45,46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 707-P AD-III	Legal Manufacturer: M/s Shanghai Huifeng Medical Instrument Co., Ltd. Building No. 2, No. 885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China FSC: China Valid till: 27/03/2023	Shadowless operating lamp (Shadowless operating lamp) Class-A Shelf Life: 05 years Model: 700LED	Deferred for provision of following: <ul style="list-style-type: none"> Essential Principle checklist. Labels. FQA certificate.
21.	M/s Medic Ally (Pvt) Ltd, 403- Nishter Block, Allama Iqbal Town, Lahore ELI: 00719 3311-P	Legal Manufacturer: M/s SceneRay Co., Ltd, C16, BioBay, 218 xinghu St., Slp.215123, Suzhu, China. FSC: China Valid till: 2022/03/23	SceneRay DBS System (Deep Brain Stimulation Device) Class-D Shelf Life: 24 months Codes & Sizes: As per FSC	Deferred for provision of valid embassy attested FSC in the country of origin and ISO 13485 and FSC of any reference country or CE mark documents.
22.	M&M Pharma 1st Floor, Javaid Plaza Opposit+B2147: L2147e Gate No. 2 Pepsi factory, Gurumangat Road, Gulberg II, Lahore.	Legal Manufacturer: Medical Plastic Factory Medioplast, Lot N3-2, Dai Dong, Hoan Son Industrial Zone, Hoan Son Ward, Tien Duc Dist, Bac Ninh Province	AD Syringe KI (Sterile auto disable syringe, needle lock) Class-B Shelf Life: 5 years Size: 0.5ml	Deferred for provision of following: <ul style="list-style-type: none"> FSC of any SRA country is not provided. Essential Principle checklist. Declaration of conformity to be printed on manufacturer's letter

	ELI: 3570-P	FSC issuance 30-08-2021 valid for 36 Months		head duly filled and signed by responsible person.
23.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G- 3, Khayaban-e- Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [629-C]	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA 91325 USA FSC: copy Netherlands Valid Till: 26-5- 2024	Guardian Link 3 Transmitter Kit Codes: MMT-7810 MMT-7811 MMT-7715 MMT-7736L MMT-7512 Class:B Shelf Life: 3 Years Fee: 25000 Challan No.040916210	Deferred for submission of the following: 1. Codes applied on Form 7A is different then present on the FSC clarify or revise Form 7A. 2.Submit embassy attested valid FSC 3. Provide valid and notarized LOA ,ISO 13485 and FQA, since only copies provided. 4. Provide stability studies and EPSP along with undertaking on stap paper as part of the Form7A.
24.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G- 3, Khayaban-e- Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [740-C]	Medtronic INC 710 Medtronic Pkwy Minneapolis MN USA Medtronic Perfusion Systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC USFDA original Valid till 16-02-2023	DLP Adapter Y-type with equal legs Class: D Shelf Life: 3 Years	Deferred for provision of the following: - 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached. 2.Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA ,ISO 13485 and FQA, Design Examinatio certificaite and DOC . 4. Provide EPSP
25.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-	Medtronic INC 710 Medtronic Pkwy Minneapolis MN USA FSC USFDA	MI Ar Cannula Class: D Shelf Life: 3 Years	Deferred for provision of the following: - 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached.

	3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [741-C]	original Valid till 16-02-2023		2.Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA ,ISO 13485 and FQA, Design Examination certificate and DOC . 4. Provide EPSP
26.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [799-C]	Medtronic Inc 710 Medtronic Pkwy Minneapolis, MN USA FSC USFDA 22-02-2023	Pediatric Aortic Root Cannulae Class: D Shelf Life: 3 Years	Deferred for provision of the following: - 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached. 2.Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA ,ISO 13485 and FQA, Design Examination certificate and DOC . 4. Provide EPSP
27.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [800-C]	Medtronic Inc 710 Medtronic Pkwy Minneapolis, MN USA FSC USFDA 22-02-2023	Medical Adhesive Class: B Shelf Life: 3 Years	Deferred for provision of following: 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached. 2.Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA ,ISO 13485 and FQA, and DOC . 4.Provide EPSP
28.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-	Medtronic Inc 710 Medtronic Pkwy Minneapolis, MN USA	Wrench Kit Class: B Shelf Life: 3 Years	Deferred for provision of following: 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached.


	3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [803-C]	FSC USFDA 22-02-2023		2. Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA, ISO 13485 and FQA, and DOC. 4. Provide EPSP
29.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [964-C]	Medtronic Inc 710 Medtronic Parkway Minneapolis, Mn 55432 USA Medtronic Inc 8200 coral sea street ne mounds mn USA FSC: US FDA Valid Till: 22-6-2022	Screw-In Pacing Leads Class: D Shelf Life: 3 Years	Deferred for provision of the following: - 1. Submit fee of Rs.50000/- for the applied product. Since fee slip of another product attached. 2. Submit embassy attested valid FSC of the product applied. 3. Provide valid and notarized LOA, ISO 13485 and FQA, Design Examination certificate and DOC. 4. Provide EPSP
30.	M/s Medtronic Pakistan (Private) Limited, Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) [543-6A]	Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA Medtronic Perfusion Systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC: USA Valid Till: 1-4-2022	DLP ANTEGRADE / RETTROGRADE (STOPCOCK) ADAPTER 13001 Class: B Shelf Life: 3 Years Fee: 25000 Challan No. 190659491438	Deferred for provision of following: 1. Submit embassy attested valid FSC of the product applied. 2. Provide valid and notarized LOA, ISO 13485 and FQA, and DOC. 3. Stability studies not provided
31.	M/s Genus, 220, Block:3 DMCHS, S. Abdul Tawwab road, Karachi Pakistan (ELI-00038)	Shanghai Kindly Medical Instruments Co., Ltd NO. 925, Jinyuan No. 1 Road, Shanghai China	G-Ducer F (Femoral Introducer Set) Class B Shelf Life: 3 Years	Deferred for the provision and clarification of the followings: • The brand name G-Ducer F does not found in any of the administrative document like LoA, FSC nor in the technical

	3982	FSC: Germany Issued 29.08.2019		<p>document like stability study data and report DoC etc.</p> <ul style="list-style-type: none"> • Generic name applied as 'Femoral Introducer set' but documents shows name 'Introducer set' only. • Required Codes of the applied product not provided. • Just copies of LoA, FSC of China(expired), FSC of Germany, ISO 13485(expired), FQAS certificate, DoC are attached, original documents are not attached.
32.	<p>M/s Genus, 220, Block:3 DMCHS, S. Abdul Tawwab road, Karachi Pakistan (ELI-00038)</p> <p>3983</p>	<p>Shanghai Kindly Medical Instruments Co., Ltd NO. 925, Jinyuan No. 1 Road, Shanghai China</p> <p>FSC: Germany Issued 29.08.2019</p>	<p>G-Ducer R (Radial Introducer Set)</p> <p>Class B Shelf Life: 3 Years</p>	<p>Deferred for the provision and clarification of the followings: -</p> <ul style="list-style-type: none"> • The brand name G-Ducer R does not found in any of the administrative document like LoA, FSC nor in the technical document like stability study data and report DoC etc. • Generic name applied as 'Radial Introducer set' but documents shows name 'Introducer set' only. • Required Codes of the applied product not provided. • Just copies of LoA, FSC of China(expired), FSC of Germany, ISO 13485(expired), FQAS certificate, DoC are attached, original documents are not attached.
33.	<p>M/s Genus, 220, Block:3 DMCHS, S. Abdul Tawwab</p>	<p>Shanghai Kindly Medical Instruments Co., Ltd</p>	<p>G - Fold (3 Port Manifold Kit)</p> <p>Class B</p>	<p>Deferred for the provision and clarification of the followings: -</p>

road, Karachi Pakistan (ELI-00038)	NO. 925, Jinyuan No. 1 Road, Shanghai China	Shelf Life: 3 Years	<ul style="list-style-type: none"> The brand name G-Fold does not found in any of the administrative document like LoA, FSC nor in the technical document like stability study data and report DoC etc. Required Codes of the applied product not provided. Just copies of LoA, FSC of China(expired), FSC of Germany, ISO 13485(expired); FQAS certificate; DoC are attached; original documents are not attached.
3984	FSC: Germany Issued 29.08.2019		

2. In the light of decision of MDB in its 37th meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notarized/Embassy attested documents at the time of submission of application for registration/enlistment and is expired during the processing of applications, such firms shall only submit valid and original (where applicable) documents.

3. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.


(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB