

Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health and Family Welfare

Government of India

(Medical Devices and Diagnostics Division)

Email: ddcimdcdsco@nic.in

Food & Drugs Administration Bhawan,

Kotla Road, New Delhi.

F.No. 29/Misc./03/2023-DC(134)

Date: 08th May 2023

MEDICAL DEVICE ALERT

DEVICE

HOYA Vivinex Toric IOLs (Model Numbers: XY1AT2, XY1AT3, XY1AT4, XY1AT5, XY1AT6, XY1AT7, XY1AT8 and XY1AT9)

Manufactured from June 2022 to January 2023 (List of affected batches in India attached)

BACKGROUND

HOYA Surgical Optics is recalling HOYA Vivinex iSert Toric IOLs from a specified manufacturing period (June 2022 to January 2023). Recall Action Classification Class II, Recall Action Commencement Date 12.04.2023.

Reason for Recall

HOYA Surgical Optics is recalling HOYA Vivinex iSert Toric IOLs from a specified manufacturing period (June 2022 to January 2023) and have received customer's complaints in Australia and Japan, with reports of damage (such as scratches) and fragment adhesion on the IOL optic surface. Following the initial investigation of returned samples, HOYA identified that damage had occurred to the nozzle tip of the iSert injector during Toric IOL implantation. This damage might have led to the reported scratches on the optic surface and polypropylene (PP) resin fragments from inside the injector tip to adhere to the IOL surface (PP adhesion).

FURTHER DETAILS & CONTACTS

Recall Action Notification for Hoya Vivinex insert Toric IOLs from Department of Health, Therapeutics Goods Administration, Australian Government herewith attached with this alert.

M/s. HOYA Medical India Pvt. Ltd.,

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Mathura Road, South Delhi

New Delhi 110044 India

hoyasurgicaloptics.com

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HOYA.com/SurgicalOptics

Date: 28-April-2023

Hoya Medical Affected batch details

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)									
HOYA Vivinex Toric XY1A	ES483	1	2JM501D3									
	ESS11	19	2FM60015	2FM60016	2HM60023	2JM60029	2JM60035	2JM60068	2JM60071	2JM60072		
			2JM60073	2JM600A3	2JM600A4	2JM600A5	2JM600CA	2JM600D1	2JM600D2	2KM600C1		
			2KM600E2	2LM60093	2LM600D4							
	ESS14	89	2EM600D2	2EM600D3	2EM600D4	2EM600D5	2EM600D6	2EM600D7	2EM600D8	2EM600D9		
			2EM600DA	2EM600E1	2EM600E2	2EM600E3	2EM600E4	2EM600E5	2EM600E6	2EM600E7		
			2EM600E8	2EM600EA	2EM600F1	2EM600F2	2EM600F3	2EM600H8	2EM600K4	2EM600K5		
			2EM600K6	2EM600K8	2EM600L2	2EM600L4	2EM600L5	2EM600L6	2EM600L7	2EM600L8		
			2EM600L9	2EM600LA	2EM600M1	2EM600M2	2EM600N1	2EM600N3	2EM600N4	2EM600N5		
			2EM600P3	2EM600P4	2EM600P5	2EM600P6	2EM600P7	2EM600P8	2EM600P9	2EM600PA		
			2EM600Q1	2EM600Q2	2EM600S7	2EM600S8	2EM600S9	2EM600SA	2EM600T1	2EM600T2		
			2EM600T3	2EM600T4	2EM600T5	2FM60041	2FM60042	2FM60073	2FM60074	2FM60083		
			2FM60085	2FM60087	2FM60088	2FM600JA	2FM600K1	2FM60106	2FM60107	2FM60108		
			2FM60109	2FM6010A	2FM60112	2FM60113	2FM60114	2FM60115	2FM60116	2GM60031		
			2GM60032	2GM60096	2GM60097	2GM600E5	2GM600E6	2GM600E7	2GM600E8	2KM600J2		
			2LM600F8									
	ESS25	53	2EM60181	2EM60197	2EM60198	2FM601K6	2FM601K8	2FM601K9	2FM601KA	2FM601L1		
			2FM601L2	2FM601L3	2FM601L4	2FM601L5	2FM601L6	2FM601L7	2FM601L8	2FM601N8		
			2FM601N9	2FM601NA	2FM602K1	2FM602K2	2GM60111	2GM60141	2GM60142	2GM60143		
			2GM60144	2GM60177	2GM60178	2GM60179	2HM60061	2HM60065	2HM60066	2HM60087		
			2JM600H6	2JM600H7	2JM600H8	2JM600H9	2JM600HA	2JM600J3	2JM600J4	2JM600J5		
			2JM600J6	2JM600J8	2JM600J9	2JM600P5	2JM600P6	2JM600P7	2JM600P8	2JM600W8		
			2JM600W9	2JM600WA	2JM600X1	2JM600Y9	2JM600YA					
ESS27	131	2FM60281	2FM60286	2FM60287	2FM60288	2FM60289	2FM6028A	2FM60291	2FM60292			
		2FM602W1	2FM602W2	2FM602W3	2FM602W4	2FM602W5	2FM602W6	2FM602W7	2FM602W8			
		2FM602W9	2FM602WA	2GM601A1	2GM601A2	2GM601A3	2GM601A4	2GM601A5	2GM601A6			
		2GM601A7	2GM601AA	2GM601B1	2GM601B2	2GM601B3	2GM601B4	2GM601B5	2GM601B6			
		2GM601B7	2GM601B9	2GM601C1	2GM601C2	2GM601C4	2GM601C5	2GM601C6	2GM601C7			
		2GM601C8	2GM601C9	2GM601CA	2GM601D1	2GM601D2	2GM601D3	2GM601D4	2GM601D5			
		2GM601D7	2GM601E1	2GM601E2	2GM601E5	2GM601E7	2GM601E8	2GM601F1	2GM601F2			
		2GM601F3	2GM601F4	2GM601F5	2GM601F7	2GM601F8	2GM601F9	2GM601FA	2GM601G1			
		2GM601G2	2GM601G3	2GM601G4	2GM601G5	2GM601G6	2HM600T1	2HM600T2	2HM600T3			
		2HM600T4	2HM600T6	2HM600T8	2HM600Z1	2HM600Z2	2HM600Z3	2HM600Z4	2HM600Z5			
ESS57	131	2HM600Z6	2HM600Z7	2HM600Z8	2HM600Z9	2HM600ZA	2HM60141	2HM60143	2HM60144			
		2HM60145	2HM60146	2HM60147	2HM60148	2HM60149	2HM60151	2HM60152	2HM60153			
		2HM60155	2HM60156	2HM60157	2HM60158	2HM60159	2HM60162	2HM60164	2HM60165			
		2HM60166	2HM60169	2HM6016A	2HM60171	2HM601H1	2HM601H2	2HM601H3	2HM601H4			
		2HM601H5	2HM601H6	2HM601H7	2HM601H8	2HM601H9	2HM601HA	2HM601J1	2HM601J2			
		2HM601J3	2HM601J4	2HM601J5	2HM601J6	2HM601J7	2HM601J8	2JM60131	2JM60132			
		2JM60133	2LM600J1	2LM600J2								
		2EM601J1	2EM601J2	2EM601J3	2EM601J4	2EM601J5	2EM601J7	2EM601J8	2EM601K1			
		2EM601Q9	2EM601QA	2EM601R1	2EM601R2	2EM601R3	2EM601R4	2EM601R5	2EM601R7			
		2EM601R8	2EM601R9	2EM601SA	2EM601T2	2EM60201	2EM60203	2EM60204	2EM60205			
ESS57	131	2EM60207	2EM60208	2EM6020A	2EM60211	2EM60212	2EM60213	2EM60214	2EM60215			
		2EM60216	2EM60217	2EM6021A	2EM60221	2EM60222	2EM60223	2EM60224	2EM60225			
		2EM60226	2EM60227	2EM60231	2EM60232	2EM60233	2EM60234	2FM603S2	2FM603S3			
		2FM603S4	2FM603S5	2FM603S7	2FM603S8	2FM60418	2FM60419	2FM6041A	2FM60421			
		2FM60423	2FM60424	2FM60425	2FM60426	2FM60427	2FM60428	2FM60435	2FM60436			
		2FM60437	2FM60438	2FM60439	2FM6043A	2FM60441	2FM60442	2FM60443	2FM60444			
		2FM60445	2FM60446	2FM60447	2FM60448	2FM60449	2FM6044A	2FM60451	2FM60452			
		2FM60453	2FM60454	2FM60455	2FM60456	2FM60457	2FM60458	2FM60459	2FM6045A			
		2FM604C5	2FM604C6	2FM604C7	2FM604C8	2FM604C9	2FM604CA	2FM604D1	2FM604D2			
		2FM604D3	2FM604D4	2FM604G1	2FM604G2	2FM604G3	2FM604G4	2FM604G5	2FM604G6			
ESS57	131	2JM60171	2JM601A3	2JM601A4	2JM601A5	2JM601A6	2JM601A7	2JM601A8	2JM601C4			
		2JM601C5	2JM601C6	2JM601C7	2JM601C8	2JM601C9	2JM601E1	2JM601E2	2JM601E3			
		2JM601E6	2JM601F4	2JM601F5	2JM601F6	2JM601F7	2JM601J1	2JM601J2	2JM601J3			
		2JM601J5	2JM601M2	2JM601M3								

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)						
ES569	69	2EM601D2	2EM601D4	2EM601D6	2EM601D7	2EM601D9	2EM601E1	2EM601E2	2EM601E4
		2EM601E6	2EM601E7	2EM601E8	2EM601E9	2EM601EA	2EM601F2	2EM601F4	2EM601F7
		2EM601F8	2EM60262	2EM60274	2EM60275	2EM60277	2EM60278	2EM60279	2EM6027A
		2FM603M1	2FM603M2	2FM603M3	2FM603M4	2FM603M5	2FM603M6	2FM603M7	2FM603M8
		2FM603MA	2FM603N2	2FM603N3	2FM603N4	2FM603N5	2FM603N6	2FM603N7	2FM603N8
		2FM603N9	2FM603NA	2FM603P1	2FM603P2	2FM605E7	2FM605F1	2FM601R9	2GM601RA
		2GM602E8	2GM602G5	2GM602M1	2GM602M2	2GM602P2	2GM602P4	2GM602P7	2GM602R5
		2GM602R7	2GM602R8	2GM602R9	2GM602S6	2GM602S7	2GM602S8	2GM602S9	2GM602SA
		2GM602T1	2GM602T2	2GM602T3	2GM60379	2GM6037A			
ES578	5	2GM603G2	2GM603G3	2GM603G5	2HM60227	2JM601W4			
ES579	118	2EM602S7	2EM602S8	2EM602E3	2EM602E4	2EM602E5	2EM602E6	2EM602E9	2EM602F1
		2EM602F2	2EM602F3	2EM602F5	2EM602F6	2EM602F7	2EM602F8	2EM602F9	2EM602FA
		2EM602G2	2EM602G4	2EM602G5	2EM602G9	2EM602GA	2EM602H3	2EM602H4	2EM602H5
		2EM602H7	2EM602J1	2EM602J2	2EM602J3	2FM604X2	2FM604X3	2FM604X5	2FM60548
		2FM60549	2FM60551	2FM60567	2FM60568	2FM60569	2FM60571	2FM60573	2FM60681
		2FM60682	2FM60683	2FM60684	2FM60685	2FM60686	2FM60687	2FM60688	2FM60689
		2FM6068A	2FM60691	2FM60692	2FM60693	2FM60694	2FM60695	2FM60696	2FM60697
		2FM60698	2FM60699	2FM606A1	2FM606A2	2FM606A3	2FM607D1	2FM607D2	2FM607D3
		2FM607D4	2FM607D5	2FM607D6	2FM607D7	2FM607D8	2FM607D9	2FM607DA	2GM601T1
		2GM601T2	2GM601T3	2GM60231	2GM60232	2GM60233	2GM602A8	2GM603P1	2GM603P3
		2GM603P4	2GM603P5	2GM603P7	2GM603P8	2GM603P9	2GM603PA	2GM603Q2	2GM603Q4
		2GM603Q5	2GM603Q6	2GM603Q8	2GM603Q9	2GM603QA	2GM603R1	2GM603R2	2GM603R3
		2GM603R4	2GM603R5	2HM601L1	2HM601L2	2HM601L3	2HM601P1	2HM601P2	2HM60231
		2HM60232	2HM60234	2HM60237	2HM60238	2HM6023A	2HM60245	2HM60246	2HM60248
		2HM60253	2HM60254	2JM601P1	2JM601PA	2JM601Q1	2JM601Q2		
ES584	107	2EM602K1	2EM602K2	2EM602K3	2EM602K4	2EM602K5	2EM602K7	2EM602K8	2EM602K9
		2EM602KA	2FM60814	2FM60816	2FM60817	2FM60818	2FM60819	2FM60821	2FM60822
		2FM60823	2FM60824	2FM60826	2FM60827	2FM60828	2FM60829	2FM6082A	2FM60831
		2FM60832	2FM60833	2FM60834	2FM60836	2FM60837	2FM60839	2FM6083A	2FM608R1
		2FM608R2	2FM608R3	2FM608R4	2FM608R5	2FM608R6	2FM608R7	2FM608R8	2FM608R9
		2FM608RA	2FM608S1	2FM608S2	2FM608S3	2FM608S4	2FM608S5	2FM608S6	2FM608S7
		2FM608S8	2FM608SA	2FM608T1	2FM608T2	2FM608T3	2FM609R2	2FM609R3	2FM609R4
		2FM609R5	2FM609R6	2FM609R7	2FM609R8	2FM609R9	2FM609RA	2FM609S1	2FM609S2
		2FM609S3	2FM609S4	2FM609S5	2FM609S6	2FM609S7	2FM609S8	2FM609S9	2FM609SA
		2FM609T1	2FM609T2	2FM609W1	2FM609W3	2FM609W4	2FM609W5	2FM609W6	2FM609W7
		2FM609W8	2FM609W9	2FM609WA	2FM609X1	2FM609X2	2FM609X3	2FM609X4	2FM609X6
		2FM609X7	2FM609X8	2FM60A61	2FM60A62	2FM60A63	2FM60A64	2FM60A8A	2FM60A91
		2FM60A92	2FM60A93	2FM60A94	2FM60A95	2FM60A96	2FM60A97	2FM60A98	2FM60A99
		2FM60A9A	2FM60AG1	2FM60AG3					
ES604	41	2EM602M2	2EM602M3	2EM602M4	2EM602M9	2FM60AT4	2FM60AT5	2GM603X1	2GM603X2
		2GM603X3	2GM603X4	2GM60417	2GM60418	2GM60419	2GM6041A	2GM60432	2GM60434
		2GM60436	2GM60437	2GM604E4	2GM604E5	2GM604E6	2GM604E7	2GM604E8	2GM604F2
		2GM604F3	2GM604F4	2GM604F5	2GM604F6	2GM604F7	2GM602S4	2HM602S6	2HM602T3
		2HM602T4	2HM602T5	2HM602VA	2HM602W4	2HM602W6	2JM60224	2JM60225	2JM60227
		2KM601D9							
ES605	114	2EM602P4	2EM602P5	2EM602P6	2EM602P7	2EM602P8	2EM602P9	2EM602PA	2FM60AZ1
		2FM60AZ2	2FM60AZ3	2FM60AZ6	2FM60AZ7	2FM60AZ8	2FM60AZ9	2FM60B01	2FM60B02
		2FM60B03	2FM60B05	2FM60B06	2FM60B07	2FM60B08	2FM60B09	2FM60B11	2FM60B12
		2FM60B13	2FM60B14	2FM60B15	2FM60B16	2FM60B17	2FM60B18	2FM60B19	2FM60B1A
		2FM60B21	2FM60B22	2FM60B23	2FM60B24	2FM60B25	2FM60B28	2FM60B33	2FM60B34
		2FM60B35	2FM60B36	2FM60B37	2FM60B38	2FM60B39	2GM604T7	2GM604T8	2GM604T9
		2GM604TA	2GM604U7	2GM604U8	2GM604U9	2GM605C2	2GM605C3	2GM605C4	2GM605C5
		2GM605F1	2GM605F2	2GM605F3	2GM605F4	2GM605F5	2GM605F6	2GM605F7	2GM605F8
		2HM603Q4	2HM603Q5	2HM603Q6	2HM603Q7	2HM603Q8	2HM603Q9	2HM603QA	2HM603R1
		2HM603R2	2HM603R3	2HM603R4	2HM603R5	2HM603R7	2HM603R8	2HM603RA	2HM603TA
		2HM603U1	2HM603U2	2HM603U3	2HM603U4	2HM603W1	2HM603W2	2HM603W3	2HM603W4
		2HM603W5	2HM603W6	2HM603W8	2HM603W9	2HM603Z5	2HM603Z6	2HM60444	2HM60446
		2HM60447	2HM60448	2HM60449	2HM60485	2HM60487	2HM60488	2HM60489	2HM6048A
		2HM60491	2HM60492	2HM60493	2HM60494	2HM60495	2HM60496	2HM60497	2HM60498
		2HM60499	2HM6049A						
ES606	61	2EM603F5	2EM603F6	2EM603F7	2EM603F8	2EM603FA	2EM603G1	2EM603G2	2EM603G3
		2EM603G4	2EM603G5	2EM603G6	2EM603G7	2EM603G8	2EM603G9	2EM603GA	2EM603H1
		2EM603H4	2EM603H6	2EM603H7	2EM603H8	2GM606R8	2GM606R9	2GM606S1	2GM606S3
		2GM606S4	2GM606S5	2GM606S7	2GM606S8	2GM606S9	2HM604F2	2HM604F3	2HM604F4
		2HM604F5	2HM604F6	2HM604F7	2HM604F8	2HM604F9	2HM604G1	2HM604G2	2HM604G3
		2HM604G4	2HM604G5	2HM604K3	2HM604K4	2HM604K5	2HM604K6	2HM604K7	2HM604K8
		2JM60294	2JM60295	2JM60296	2JM60297	2JM60298	2JM602C8	2JM602C9	2JM602CA
		2JM602D1	2JM602D2	2JM602D3	2JM602D4	2JM602D5			
ES607	59	2EM70011	2EM70043	2EM70044	2EM70045	2EM70046	2EM70047	2EM70048	2EM70049
		2EM7004A	2EM70051	2EM70052	2EM70053	2EM70054	2EM70055	2EM70056	2EM70057
		2EM70069	2GM607N8	2GM607N9	2GM607NA	2HM60692	2HM60693	2HM60694	2HM60695
		2HM60696	2HM60697	2HM70011	2HM70012	2HM70013	2HM70014	2HM70015	2HM70016
		2HM70017	2HM70075	2HM70076	2HM70077	2HM70078	2HM70079	2HM7007A	2HM70081
		2HM70082	2HM70083	2HM70084	2HM70086	2HM700C6	2HM700C7	2HM700C8	2HM700C9
		2HM700CA	2HM700D3	2HM700D4	2HM700D5	2HM700D6	2HM700D7	2HM700G7	2HM700G8
		2JM70041	2JM70042	2JM70044					
ES617	2	2KM7006A	2KM70071						

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)							
	E5619	75	2EM70071	2EM70072	2EM70073	2EM70076	2EM70077	2EM70078	2EM70079	2EM7007A
			2EM70081	2EM70082	2EM70083	2EM70084	2EM70085	2EM70086	2EM70087	2EM70088
			2EM70089	2EM70091	2EM70092	2EM70093	2EM70094	2EM70095	2EM70096	2EM70097
			2EM70098	2EM70099	2EM700A1	2EM700A2	2EM700A3	2EM700A4	2EM700A5	2EM700A6
			2EM700A7	2EM700A8	2EM700A9	2EM700B1	2EM700B4	2EM700B5	2EM700B6	2EM700C1
			2EM700C2	2EM700C3	2EM700C4	2EM700C5	2EM700C6	2EM700C7	2EM700C8	2EM700C9
			2EM700CA	2EM700D1	2EM700D2	2EM700D3	2EM700D4	2EM700D5	2EM700D6	2EM700D7
			2EM700D8	2EM700D9	2EM700F6	2EM700F7	2EM700F8	2EM700F9	2JM700T2	2JM700T3
			2JM700T4	2JM700T5	2JM700T6	2JM70165	2JM70166	2JM70167	2JM70168	2JM70169
			2JM70171	2JM70173	2JM70174					
	E5622	197	2EM700G1	2EM700G2	2EM700G4	2EM700G5	2EM700G6	2EM700G8	2EM700G9	2EM700GA
			2EM700H1	2EM700H2	2EM700H5	2EM700H7	2EM700H8	2EM700H9	2FM700A5	2FM700A6
			2FM700A8	2FM700A4	2FM700A1	2FM700A2	2FM700A3	2FM700A4	2FM700A5	2FM700A6
			2FM700A7	2FM700A8	2FM700A9	2FM700A9	2FM700B1	2FM700B2	2FM700B3	2FM700B4
			2FM700B5	2FM700B6	2FM700B8	2FM700B9	2FM700BA	2FM700C1	2FM700C2	2FM700C3
			2FM700C4	2FM700C5	2FM700C6	2FM700C7	2FM700F1	2FM700F2	2FM700F3	2FM700F4
			2FM700F6	2FM700F7	2FM700F8	2FM700F9	2FM700FA	2FM700G1	2FM700G2	2FM700G4
			2FM700G5	2FM700G6	2FM700G7	2FM700G8	2FM700G9	2FM700GA	2FM700H1	2FM700H2
			2FM700H3	2FM700I1	2FM700I2	2FM700I3	2FM700I4	2FM700I5	2FM700I6	2FM700I7
			2FM700K1	2FM700K2	2FM700K3	2FM700K4	2FM700K5	2FM700K6	2FM700K7	2FM700K8
			2GM703K3	2GM703K4	2GM703K5	2GM703K6	2GM703K7	2GM703K8	2GM703K9	2GM703KA
			2GM703L1	2GM703L3	2GM703L4	2GM703L5	2GM703L6	2GM703L8	2GM703LA	2GM703M1
			2GM703M2	2GM703M3	2GM703M4	2GM703M5	2GM703M6	2GM703M7	2GM703M8	2GM703M9
			2GM703V8	2GM703V9	2GM703VA	2GM703W1	2GM703W2	2GM703W3	2GM703W4	2GM703W5
			2GM703W6	2GM703W7	2GM703W8	2GM703W9	2GM703WA	2GM703X1	2GM703X2	2GM703X3
			2GM703X4	2GM703X5	2GM703X6	2GM70422	2GM70423	2GM70424	2GM70425	2GM70426
			2GM70427	2GM70428	2GM70429	2GM7042A	2GM70431	2GM70451	2GM70452	2GM70455
			2GM70456	2GM70457	2GM70458	2GM70459	2GM7045A	2GM70461	2GM70462	2GM70463
			2GM70464	2GM70465	2GM70466	2GM70467	2GM70468	2GM70469	2GM7046A	2GM70471
			2GM70472	2GM70473	2GM70474	2GM70475	2GM70476	2GM70477	2GM70478	2GM70479
			2GM7047A	2GM70481	2GM70483	2GM70484	2GM70485	2HM700Q9	2HM700QA	2HM700R1
			2HM700R2	2HM700R3	2HM700R7	2HM700R8	2HM700R9	2HM700RA	2HM700S1	2HM700S2
			2HM700S3	2HM700S4	2HM700S5	2HM700S7	2HM700S8	2HM700S9	2HM700SA	2HM70123
			2HM70124	2HM70125	2HM70126	2HM70127	2HM70128	2HM70129	2HM7012A	2HM70131
2HM70135	2HM70136	2HM70137	2HM70138	2HM70139						
	E5633	72	2EM700Q1	2EM700Q2	2EM700V1	2EM700V2	2EM700V3	2EM700V4	2EM700Y4	2EM70111
			2EM70112	2EM70118	2FM700Q5	2FM700Q6	2FM700W4	2FM700W5	2FM700X9	2FM7011A
			2FM70121	2GM70607	2GM70608	2GM70609	2GM7060A	2GM70611	2GM70612	2GM70613
			2GM70614	2GM70615	2GM70616	2GM7066A	2GM70675	2GM70676	2GM706C4	2HM70183
			2HM70184	2HM70185	2HM70186	2HM70187	2HM70188	2HM70189	2HM7018A	2HM70185
			2HM70186	2HM70187	2HM70188	2HM70189	2HM7018A	2HM701C1	2HM701C2	2HM701C3
			2HM701C4	2HM701C5	2HM701C7	2HM701C8	2HM701C9	2HM701V9	2HM701Y3	2HM701Y5
			2HM701Y6	2HM701Y7	2HM701Y8	2HM701Y9	2HM701YA	2HM702V4	2HM702V5	2HM702X1
			2HM702X3	2HM702X4	2HM702X6	2JM70191	2JM70192	2JM70193	2JM70194	2JM70195
	E5642	58	2EM700L9	2EM700M1	2EM700M2	2EM700M5	2EM700M6	2EM700M7	2EM700M8	2EM700M9
			2EM700U1	2EM700U2	2EM700U4	2EM700U5	2EM700Z1	2EM700Z2	2EM700Z3	2EM70103
			2EM70104	2EM70105	2EM70106	2EM70107	2EM70108	2EM70109	2EM70123	2EM70128
			2EM70151	2EM70152	2EM70171	2EM70172	2EM70173	2EM70174	2EM70175	2EM70176
			2EM70178	2EM70179	2EM7017A	2EM70181	2EM70182	2EM70183	2EM70184	2EM70185
			2EM70187	2EM70188	2EM70189	2EM7018A	2FM70148	2HM70345	2HM70346	2HM70347
			2HM70348	2HM70349	2HM70351	2JM701G1	2JM701J7	2JM701J8	2JM701N3	2JM701N4
			2JM701S8	2JM701S9						
	E5651	247	2EM800H1	2EM800H2	2EM800H3	2EM800H4	2EM800H5	2EM800H6	2EM800H7	2EM800H8
			2EM800H9	2EM800HA	2EM800J1	2EM800J2	2EM800J3	2EM800J4	2EM800J5	2EM800J6
			2EM800J7	2EM800J8	2EM800J9	2EM800K1	2EM800K2	2EM800K3	2EM800K4	2EM800K5
			2EM800K6	2EM800K7	2EM800K8	2EM800K9	2EM800KA	2EM800L2	2EM800L3	2EM800L4
			2EM800L5	2EM800L6	2EM800L8	2EM800L9	2EM800M1	2EM800M2	2EM800M3	2EM800M4
			2EM800M5	2EM800M6	2EM800M7	2EM800M8	2EM800M9	2EM800MA	2FM800M1	2FM800M2
			2FM800M3	2FM800M4	2FM800M5	2FM800N2	2FM800N3	2FM800N4	2FM800N5	2FM800N6
			2FM800N7	2FM800N8	2FM800N9	2FM800P1	2FM800P2	2FM800P3	2FM800P4	2FM800P5
			2FM800P7	2FM800P8	2FM800P9	2FM800PA	2FM800Q1	2FM800Q2	2FM800Q3	2FM800Q5
			2FM800Q6	2FM800Q7	2FM800Q8	2FM800Q9	2FM800QA	2FM800R1	2FM800R2	2FM800R3
			2FM800R4	2FM800R5	2FM800R7	2FM800U1	2FM800U2	2FM800U3	2FM800U4	2FM800U7
			2FM800U8	2FM800UA	2GM800H1	2GM800H2	2GM800H3	2GM800H4	2GM800H5	2GM800H6
			2GM800H8	2GM800H9	2GM800HA	2GM800J1	2GM800J2	2GM800J3	2GM800J4	2GM800J5
			2GM800J6	2GM800J7	2GM800J8	2GM800J9	2GM800JA	2GM800K1	2GM800K3	2GM800K4
			2GM800K5	2GM800K6	2GM800K8	2GM800K9	2GM800KA	2GM800L1	2GM800L2	2GM800L3
			2GM800L4	2GM800L5	2GM800L6	2GM800L7	2GM800L8	2GM800L9	2GM800T1	2GM800T2
			2HM80062	2HM80063	2HM80064	2HM80065	2HM80066	2HM80067	2HM80068	2HM80069
			2HM80081	2HM80082	2HM80083	2HM80084	2HM80085	2HM80086	2HM80087	2HM80088
			2HM8008A	2HM80091	2HM80092	2HM80093	2HM80094	2HM80095	2HM800C1	2HM800C2
			2HM800C3	2HM800C4	2HM800C5	2HM800C6	2HM800C8	2HM800C9	2HM800CA	2HM800D1
			2HM800D2	2HM800D3	2HM800D4	2HM800D5	2HM800D6	2HM800G1	2HM800G2	2HM800G3
			2HM800G4	2HM800G5	2HM800G6	2HM800G7	2HM800G8	2HM800G9	2HM800H1	2HM800H2
			2HM800H3	2HM800H4	2HM800H5	2HM800H6	2HM800H7	2HM800H9	2HM800HA	2HM800J1
			2HM800J3	2HM800J4	2HM800J5	2HM800J6	2HM800J7	2HM800K1	2HM800K2	2HM800K3
			2HM800K4	2HM800K5	2HM800K6	2HM800K7	2HM800K8	2HM800K9	2HM800KA	2HM800L1
			2HM800L4	2HM800L7	2HM800L9	2HM800LA	2HM800M2	2HM800M3	2HM800M4	2HM800M5
			2HM800M6	2HM800M7	2HM800M8	2HM800M9	2HM800MA	2HM800N1	2HM800N2	2HM800N3
			2HM800N6	2HM800N7	2HM800N8	2HM800N9	2HM800P1	2HM800P2	2HM800P4	2HM800P5
			2HM800P6	2HM800P7	2HM800P8	2JM80061	2JM80062	2JM80063	2JM80065	2JM80066
			2JM80068	2JM800D1	2JM800D2	2JM800D3	2JM800D4	2JM800D5	2JM800E1	2JM800E2
			2JM800E3		2JM800E4	2JM800E5	2JM800E6	2JM800E7	2JM800E8	2JM800E9

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)										
	E5723	172	2EM80161	2EM80162	2EM80163	2EM80164	2EM80165	2EM80166	2EM80168	2EM80169			
			2EM8016A	2EM80172	2EM80173	2EM80174	2EM80175	2EM80176	2EM80177	2EM801A1			
			2EM801A2	2EM801A3	2EM801A4	2EM801A5	2EM801A6	2EM801A7	2EM801A8	2EM801A9			
			2EM801AA	2EM801B1	2EM801B2	2EM801B3	2EM801B4	2FM801B1	2FM801B2	2FM801B3			
			2FM801B4	2FM801B5	2FM801B6	2FM801B7	2FM801B8	2FM801BA	2FM801C2	2FM801C4			
			2FM801C5	2FM801C6	2FM801C7	2FM801C8	2FM801C9	2FM801CA	2FM801D1	2FM801D2			
			2FM801D3	2FM801D4	2FM801D5	2FM801D6	2FM801D7	2FM801D8	2FM801D9	2FM801DA			
			2FM801E1	2FM801E3	2FM801E4	2FM801F1	2FM801F2	2FM801F3	2FM801F4	2FM801F5			
			2FM801F6	2FM801F7	2FM801F8	2FM801F9	2FM801FA	2FM801H2	2FM801H3	2FM801H4			
			2FM801H5	2FM801H6	2FM801H7	2FM801H8	2FM801H9	2FM801HA	2FM801J1	2FM801J3			
			2FM801J4	2FM801J5	2FM801J6	2FM801J7	2FM801J9	2FM801R9	2FM801S1	2FM801S2			
			2FM801S3	2FM801S4	2FM801S5	2FM801S6	2FM801S7	2FM801S8	2FM801S9	2FM801SA			
			2FM801U5	2FM801U6	2FM801U7	2FM801U8	2GM801G1	2GM801G2	2GM801G3	2GM801G4			
			2GM801G6	2GM801G8	2GM801G9	2GM801GA	2GM801H1	2GM801H2	2GM801H3	2GM801H4			
			2GM801H5	2GM801H6	2GM801H7	2GM801S1	2GM801S2	2GM801S4	2GM801S5	2GM801S6			
			2GM801S7	2GM801S8	2GM801S9	2GM801SA	2GM801T1	2GM801T2	2GM801T3	2HM801S3			
			2HM801S4	2HM801S5	2HM801S6	2HM801S7	2HM801S8	2HM801S9	2HM801SA	2HM801T1			
			2HM801T2	2HM801T3	2HM801T4	2HM801T5	2HM801T6	2HM801T7	2HM801T8	2HM801T9			
			2HM801TA	2JM800P1	2JM800P2	2JM800P4	2JM800P6	2JM800P7	2JM800P8	2JM800P9			
			2JM800PA	2JM800R2	2JM800R3	2JM800R4	2JM800R5	2JM800R7	2JM800R8	2JM800R9			
			2JM800RA	2JM800S1	2JM800S2	2JM800S3	2JM800S4	2JM800S5	2JM800S6	2JM800T3			
			2JM800T4	2JM800T5	2JM800T6	2JM800T9							
				E5794	523	2EM90011	2EM90012	2EM90013	2EM90014	2EM90015	2EM90016	2EM90017	2EM90018
						2EM90019	2EM9001A	2EM90021	2EM90022	2EM90023	2EM90024	2EM90025	2EM90026
						2EM90027	2EM90028	2EM90033	2EM90034	2EM90035	2EM90036	2EM90037	2EM90039
						2EM9003A	2EM90041	2EM90051	2EM90053	2EM90054	2EM90055	2EM90056	2EM90057
2EM90058	2EM90059	2EM9005A				2EM90061	2EM90062	2EM90063	2EM90064	2EM90065			
2EM90066	2EM90067	2EM90068				2EM90069	2EM9006A	2EM90071	2EM900G2	2EM900G3			
2EM900H1	2EM900H2	2EM900H3				2EM900H4	2EM900H5	2EM900H6	2EM900H7	2EM900H8			
2EM900H9	2EM900HA	2EM900J1				2EM900J2	2EM900J3	2EM900J5	2EM900J6	2EM900J7			
2EM900J8	2EM900JA	2EM900K1				2EM900K2	2EM900K3	2EM900K4	2EM900K5	2EM900K6			
2EM900K7	2EM900K8	2EM900K9				2EM900KA	2EM900L2	2EM900L3	2EM900L4	2EM900L5			
2EM900L6	2EM900L7	2EM900L8				2EM900L9	2EM900X1	2EM900X2	2EM900X3	2EM900X4			
2EM900X6	2EM900X7	2EM900X8				2EM900X9	2EM900XA	2EM900Z1	2EM900Z3	2EM900Z4			
2EM900Z5	2EM900Z6	2EM900Z7				2EM900Z8	2EM900Z9	2EM900ZA	2EM90101	2EM90102			
2EM90104	2EM90105	2EM90106				2EM90107	2EM90108	2EM90109	2FM90011	2FM90013			
2FM90014	2FM90015	2FM90016				2FM90017	2FM90018	2FM90019	2FM9001A	2FM90022			
2FM90023	2FM90024	2FM90025				2FM90026	2FM90027	2FM90028	2FM90029	2FM9002A			
2FM90071	2FM90072	2FM90073				2FM90074	2FM90075	2FM90076	2FM90077	2FM90078			
2FM90079	2FM9007A	2FM90082				2FM90083	2FM90084	2FM90085	2FM90087	2FM90088			
2FM90089	2FM9008A	2FM90091				2FM90092	2FM90093	2FM90094	2FM90095	2FM90096			
2FM90097	2FM90098	2FM900B1				2FM900B2	2FM900B3	2FM900B4	2FM900B5	2FM900B6			
2FM900B7	2FM900BA	2FM900C1				2FM900C2	2FM900C3	2FM900C4	2FM900C5	2FM900C6			
2FM900C7	2FM900C8	2FM900C9				2FM900CA	2FM900D1	2FM900D2	2FM900D3	2FM900D4			
2FM900D5	2FM900D6	2FM900E3				2FM900E4	2FM900E5	2FM900E6	2FM900E7	2FM900E8			
2FM900E9	2FM900EA	2FM900F1				2FM900F2	2FM900F3	2FM900F4	2FM900F5	2FM900F6			
2FM900F7	2FM900F8	2FM900H1				2FM900H2	2FM900H3	2FM900H4	2FM900H5	2FM900H6			
2FM900H7	2FM900H8	2FM900H9				2FM900HA	2FM900J1	2FM900J2	2FM900J3	2FM900J4			
2FM900J5	2FM900J6	2FM900J8				2FM900J9	2FM900JA	2FM900K1	2FM900K2	2FM900K3			
2FM900K4	2FM900K5	2FM900K6				2FM900K7	2FM900K8	2FM900K9	2FM900KA	2FM900L1			
2FM900L3	2FM900L4	2FM900L5				2FM900L6	2FM900M1	2FM900M2	2FM900M3	2FM900M4			
2FM900M5	2FM900M6	2FM900M7				2FM900M8	2FM900M9	2FM900MA	2FM900N1	2FM900N2			
2FM900N3	2FM900N4	2FM900N6				2FM900N8	2FM900N9	2FM90181	2FM90182	2FM90183			
2FM90184	2FM90185	2FM90186				2FM90187	2FM90188	2FM90189	2FM9018A	2FM90191			
2FM90192	2FM90193	2FM90194				2FM90195	2FM90196	2FM90197	2FM90198	2FM90199			
2FM9019A	2FM901C1	2FM901C2				2FM901C3	2FM901C4	2FM901C5	2GM90011	2GM90012			
2GM90013	2GM90014	2GM90015				2GM90016	2GM90017	2GM90018	2GM90019	2GM9001A			
2GM90021	2GM90022	2GM90023				2GM90024	2GM90025	2GM90026	2GM90027	2GM90028			
2GM90029	2GM9002A	2GM90031				2GM90032	2GM90033	2GM90034	2GM90035	2GM90036			
2GM90037	2GM90038	2GM90039				2GM9003A	2GM90043	2GM90044	2GM90045	2GM90051			
2GM90053	2GM90054	2GM90055				2GM90056	2GM90057	2GM90058	2GM90059	2GM9005A			
2GM90061	2GM90062	2GM90063				2GM90064	2GM90065	2GM90066	2GM90068	2GM90069			
2GM9006A	2GM90071	2GM90072				2GM90073	2GM90074	2GM90075	2GM90076	2GM90077			
2GM90078	2GM90079	2GM9007A				2GM90081	2GM90082	2GM90083	2GM90084	2GM90081			
2GM90082	2GM90083	2GM90084				2GM90085	2GM90086	2GM90087	2GM90088	2GM90089			
2GM9008A	2GM900C1	2GM900C2				2GM900C3	2GM900C4	2GM900C6	2GM900C7	2GM900C8			
2GM900C9	2GM900CA	2GM900D1				2GM900D9	2GM900DA	2GM900E1	2GM900E2	2GM900E3			
2GM900E4	2GM900E5	2GM900E6				2GM900E7	2GM900E8	2GM900E9	2GM900EA	2GM900F1			
2GM900F2	2GM900F5	2GM901Q1				2GM901Q2	2GM901Q3	2GM901Q4	2GM901Q5	2GM901Q6			
2GM901Q7	2GM901Q8	2GM901Q9				2GM901QA	2GM901R1	2GM901R2	2GM901R3	2GM901R4			
2GM901R5	2GM901R7	2GM901R8				2GM901R9	2GM901RA	2GM901S1	2GM901S2	2GM901S3			
2GM901S4	2GM901S5	2GM901S6				2GM901S7	2GM901S9	2GM901T1	2GM901T2	2GM901T3			
2GM901T4	2GM901T5	2GM901T6				2GM901T7	2GM901T8	2GM901T9	2GM901U1	2GM901U2			
2GM901U3	2GM901U4	2GM901U5				2GM901U6	2GM901U8	2GM901U9	2GM901V1	2GM901V3			
2GM901V4	2GM901V5	2GM901V6				2GM901V7	2GM901V9	2GM901VA	2HM90011	2HM90012			
2HM90014	2HM90015	2HM90016				2HM90017	2HM90018	2HM90019	2HM90021	2HM90022			
2HM90023	2HM90024	2HM90025				2HM90026	2HM90027	2HM90028	2HM90029	2HM9002A			
2HM900R1	2HM900R2	2HM900R3				2HM900R4	2HM900R5	2HM900R6	2HM900R7	2HM900R8			
2HM900R9	2HM900S1	2HM900S2				2HM900S3	2HM900S4	2HM900S5	2HM900S6	2HM900T1			
2HM900T2	2HM900T4	2HM900T5				2HM900T6	2HM900T7	2HM900T8	2HM900T9	2HM900TA			
2HM900U1	2HM900U2	2HM900U3				2HM900U4	2HM900U5	2HM900U6	2HM900U7	2HM900U8			
2HM900U9	2HM900UA	2HM900V1				2HM900V2	2HM900V3	2HM900V4	2HM900V5	2HM900V6			
2HM900V7	2HM900V9	2HM900VA				2HM900W1	2HM900W2	2HM900W3	2HM900W4	2HM900W5			
2HM900W6	2HM900W7	2HM900W8				2HM900W9	2HM900WA	2HM900X1	2HM900X2	2HM900X4			
2HM900X5	2HM900X6	2HM900Z1				2HM900Z2	2HM900Z3	2HM900Z4	2HM900Z6	2HM900Z7			
2HM900Z8	2HM900Z9	2HM900ZA				2HM90101	2HM90111	2HM90112	2HM90114	2HM90115			
2HM90117	2HM90118	2HM90119				2HM9011A	2HM90121	2HM90122	2HM90132	2HM90133			
2HM90134	2HM90135	2HM90137											

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)										
	ES795	576	2EM900R1	2EM900R2	2EM900R3	2EM900R4	2EM900R5	2EM900R6	2EM900R7	2EM900R8			
			2EM900R9	2EM900RA	2EM900S1	2EM900S2	2EM900S3	2EM900S4	2EM900S5	2EM900S7			
			2EM900S9	2FM900P1	2FM900P3	2FM900P4	2FM900P5	2FM900P6	2FM900P7	2FM900P8			
			2FM900P9	2FM900PA	2FM900Q1	2FM900Q2	2FM900Q3	2FM900Q5	2FM900Q6	2FM900Q7			
			2FM900Q8	2FM900Q9	2FM900QA	2FM900R1	2FM900R2	2FM900R3	2FM900R4	2FM900R5			
			2FM900T1	2FM900T2	2FM900T3	2FM900U1	2FM900U2	2FM900U3	2FM900U4	2FM900U5			
			2FM900U7	2FM900U8	2FM900U9	2FM900V2	2FM900V3	2FM900V4	2FM900V5	2FM900V6			
			2FM900V8	2FM900V9	2FM900VA	2FM900W2	2FM900W3	2FM900W4	2FM900W5	2FM900W6			
			2FM900W7	2FM900W8	2FM900W9	2FM900WA	2FM900X1	2FM900X2	2FM900X3	2FM900X4			
			2FM900X5	2FM900X6	2FM900X7	2FM900X8	2FM900X9	2FM900XA	2FM900Y1	2FM900Y3			
			2FM900Y4	2FM900Y5	2FM900Y6	2FM900Y7	2FM900Y8	2FM900Y9	2FM900YA	2FM900Z1			
			2FM900Z2	2FM900Z3	2FM900Z4	2FM900Z5	2FM900Z6	2FM900Z7	2FM900Z8	2FM90101			
			2FM90102	2FM90103	2FM90104	2FM90105	2FM90106	2FM90107	2FM90108	2FM90109			
			2FM9010A	2FM90111	2FM90112	2FM90113	2FM90114	2FM90115	2FM90116	2FM90117			
			2FM90118	2FM90119	2FM9011A	2FM90121	2FM90122	2FM90123	2FM90124	2FM90125			
			2FM90126	2FM90127	2FM90128	2FM90129	2FM9012A	2FM90131	2FM90132	2FM90133			
			2FM90134	2FM90135	2FM90138	2FM90139	2FM90161	2FM90162	2FM90163	2FM90164			
			2FM90165	2FM90166	2FM90167	2FM90168	2FM90169	2FM9016A	2FM90171	2GM900H1			
			2GM900H2	2GM900H3	2GM900H4	2GM900H6	2GM900H7	2GM900H8	2GM900H9	2GM900J1			
			2GM900J2	2GM900J3	2GM900J4	2GM900J5	2GM900J6	2GM900J7	2GM900J8	2GM900JA			
			2GM900K2	2GM900K4	2GM900K5	2GM900K6	2GM900K7	2GM900K8	2GM900K9	2GM900KA			
			2GM900L1	2GM900L3	2GM900L4	2GM900N1	2GM900N3	2GM900N4	2GM900N5	2GM900N6			
			2GM900N7	2GM900N8	2GM900N9	2GM900NA	2GM900P1	2GM900P2	2GM900P3	2GM900P4			
			2GM900P5	2GM900P6	2GM900P7	2GM900P9	2GM900Q1	2GM900Q2	2GM900Q3	2GM900Q4			
			2GM900Q5	2GM900Q6	2GM900Q8	2GM900Q9	2GM900QA	2GM900R1	2GM900R2	2GM900R3			
			2GM900R4	2GM900R5	2GM900R6	2GM900R7	2GM900R8	2GM900RA	2GM900S1	2GM900S2			
			2GM900S3	2GM900S5	2GM900S6	2GM900S7	2GM900S8	2GM900T1	2GM900T2	2GM900T3			
			2GM900T4	2GM900T5	2GM900T6	2GM900T7	2GM900T8	2GM900T9	2GM900TA	2GM900U1			
			2GM900U3	2GM900U4	2GM900U5	2GM900U6	2GM900U7	2GM900U8	2GM900U9	2GM900UA			
			2GM900V1	2GM900V3	2GM900V4	2GM900V5	2GM900V6	2GM900V7	2GM900V8	2GM900V9			
			2GM900VA	2GM900W2	2GM900W3	2GM900W4	2GM900W5	2GM900W6	2GM900W7	2GM900X1			
			2GM900X2	2GM900X3	2GM900X4	2GM900X5	2GM900X6	2GM900X7	2GM900X8	2GM900Y1			
			2GM900Y3	2GM900Y4	2GM900Y5	2GM900Y6	2GM900Y7	2GM900Y8	2GM900Y9	2GM900YA			
			2GM900Z1	2GM900Z2	2GM900Z3	2GM900Z4	2GM900Z5	2GM900Z6	2GM900Z7	2GM90102			
			2GM90103	2GM90104	2GM90105	2GM90106	2GM90107	2GM90108	2GM90109	2GM9010A			
			2GM90111	2GM90112	2GM90113	2GM90114	2GM90115	2GM90116	2GM90117	2GM90118			
			2GM90119	2GM9011A	2GM90121	2GM90122	2GM90123	2GM90124	2GM90125	2GM90126			
			2GM90127	2GM90128	2GM90129	2GM9012A	2GM90131	2GM90132	2GM90133	2GM90134			
			2GM90135	2GM90136	2GM90137	2GM90138	2GM90141	2GM90142	2GM90143	2GM90145			
			2GM90146	2GM90147	2GM90148	2GM90149	2GM9014A	2GM90151	2GM90152	2GM90153			
			2GM90154	2GM90155	2GM90156	2GM90157	2GM90158	2GM90159	2GM9015A	2GM90161			
			2GM90162	2GM90163	2GM90164	2GM90165	2GM90166	2GM90167	2GM90169	2GM9016A			
			2GM90171	2GM90172	2GM90173	2GM90174	2GM90175	2GM90176	2GM90177	2GM90178			
			2GM90179	2GM9017A	2GM90181	2GM90182	2GM90183	2GM90184	2GM90185	2GM90186			
			2GM90187	2GM90188	2GM90189	2GM9018A	2GM90191	2GM90192	2GM90193	2GM90194			
			2GM90195	2GM90196	2GM90197	2GM90198	2GM90199	2GM9019A	2GM901A1	2GM901A2			
			2GM901A3	2GM901A4	2GM901A5	2GM901A6	2GM901A7	2GM901A8	2GM901A9	2GM901AA			
			2GM901B1	2GM901B2	2GM901B3	2GM901B4	2GM901B5	2GM901B6	2GM901B8	2GM901B9			
			2GM901C2	2GM901C3	2GM901C4	2GM901C5	2GM901C6	2GM901C8	2GM901C9	2GM901CA			
			2GM901D1	2GM901D2	2GM901D3	2GM901D4	2GM901D5	2GM901D6	2GM901D7	2GM901D8			
			2GM901D9	2GM901DA	2GM901E1	2GM901E2	2GM901E3	2GM901E4	2GM901E5	2GM901E6			
			2GM901E7	2GM901E8	2GM901E9	2GM901EA	2GM901F2	2GM901F3	2GM901F4	2GM901F5			
			2GM901F6	2GM901F7	2GM901F8	2GM901F9	2GM901FA	2GM901G1	2GM901G2	2GM901G3			
			2GM901G4	2GM901G5	2GM901G6	2GM901G7	2GM901G8	2GM901H1	2GM901H3	2GM901H4			
			2GM901H5	2GM901H6	2GM901H7	2GM901H8	2GM901H9	2GM901K1	2GM901K2	2GM901K3			
			2GM901K4	2GM901K5	2GM901K6	2GM901K7	2GM901K8	2GM901K9	2GM901KA	2GM901L1			
			2GM901L2	2GM901L3	2GM901L4	2GM901L5	2GM901L6	2GM901L7	2GM901L8	2GM901L9			
			2GM901LA	2GM901M1	2GM901M2	2GM901M3	2GM901M4	2GM901M5	2GM901M6	2GM901M7			
			2GM901M8	2GM901M9	2GM901MA	2GM901N2	2GM901N3	2GM901N4	2GM901N5	2GM901N6			
			2GM901N7	2GM901N8	2GM901NA	2GM901P1	2GM901P2	2GM901P3	2GM901P4	2GM901P5			
			2GM901P7	2GM901P8	2GM901P9	2GM901PA	2HM90031	2HM90032	2HM90033	2HM90035			
			2HM90037	2HM90038	2HM90039	2HM9003A	2HM90041	2HM90042	2HM90043	2HM90044			
			2HM90045	2HM90046	2HM90047	2HM90049	2HM9004A	2HM90051	2HM90052	2HM90053			
			2HM900B1	2HM900B2	2HM900B3	2HM900B4	2HM900B5	2HM900B6	2HM900B7	2HM900B8			
			2HM900B9	2HM900C1	2HM900C2	2HM900C3	2HM900C4	2HM900C5	2HM900C6	2HM900C7			
			2HM900C8	2HM900CA	2HM900D1	2HM900D2	2HM900D4	2HM900D5	2HM900D6	2HM900D7			
			2HM900D8	2HM900D9	2HM900K1	2HM900K3	2HM900K4	2HM900K5	2HM900K6	2HM900K7			
			2HM900K8	2HM900L1	2HM900L3	2HM900L4	2HM900L5	2HM900L6	2HM900L9	2HM900M1			
			2HM900M2	2HM900M3	2HM900M4	2HM900M7	2HM900M9	2HM900MA	2HM900N2	2HM900N3			
			2HM900N4	2HM900N5	2HM900N6	2HM900N7	2HM900N8	2HM900P1	2HM900P2	2HM900P3			
			2HM900P4	2HM900P5	2HM900P6	2HM900P7	2HM900P8	2HM900P9	2HM900PA	2HM900Q1			
			2HM900Q2	2HM900Q3	2HM900Q4	2HM900Q5	2HM900Q6	2HM900Q7	2HM900Q8	2HM900Q9			
				ES838	198	2EM903J1	2EM903J3	2EM903J4	2EM903J5	2EM903L1	2EM903L2	2EM903L3	2EM903L4
						2EM903L5	2EM903L6	2EM903L7	2EM903L8	2EM903M1	2EM903M2	2EM903M4	2EM903M5
						2FM905U1	2FM905U2	2FM905U3	2FM905U5	2FM905U6	2FM905U7	2FM905X1	2FM905X2
						2FM905X4	2FM905X5	2FM905X7	2FM905X8	2FM905X9	2FM905XA	2FM905Y1	2FM905Y2
						2FM905Y3	2FM905Y4	2FM905Y5	2FM905Y6	2FM905Y8	2FM905Y9	2GM906U1	2GM906U2
						2GM906U3	2GM906U4	2GM906U5	2GM90701	2GM90702	2GM90703	2GM90704	2GM90707
						2GM90708	2GM90709	2GM90711	2GM90712	2GM90713	2GM90714	2GM90716	2GM90717
						2GM90718	2GM90719	2GM90721	2GM90722	2GM90724	2GM90725	2GM90726	2GM90727
						2GM90728	2GM90729	2GM90731	2GM90733	2GM90734	2GM90735	2GM90736	2GM90737
						2GM90761	2GM90762	2GM90763	2GM90764	2GM90765	2GM90766	2GM90767	2GM90768
						2GM90769	2GM90771	2GM90772	2GM90774	2GM90775	2GM90777	2GM90779	2GM9077A
						2GM90781	2GM90782	2GM90783	2GM90784	2GM90785	2GM90786	2GM90787	2GM90788
						2GM90789	2GM9078A	2HM905S1	2HM905S2	2HM905T1	2HM905T2	2HM905T3	2HM905T4
						2HM905T5	2HM905T6	2HM905T7	2HM905T8	2HM905V1	2HM905V2	2HM905V3	2HM905V4
						2HM90632	2HM90633	2HM90634	2HM90635	2HM90636	2HM90637	2HM90638	2HM90639
						2HM9063A	2HM90641	2HM90642	2HM90643	2HM90644	2HM90645	2HM90646	2HM90647
						2HM90648	2HM90649	2HM9064A	2HM90652	2HM90653	2HM90655	2HM90656	2HM90657

Product Name	Sterilization Batch No.	Total units	Serial No. (Present on the product label)							
			2HM90658	2HM9065A	2HM90661	2HM90662	2HM90663	2HM90664	2HM90665	2HM90666
			2HM90667	2HM90682	2HM90683	2HM90684	2HM90685	2HM90686	2HM90687	2HM90689
			2HM9068A	2HM90691	2HM90692	2HM90693	2HM90694	2HM90695	2HM90696	2HM906A1
			2HM906A2	2HM906C1	2HM906C2	2HM906C3	2HM906C4	2HM906C5	2HM906C6	2HM906C8
			2HM906C9	2JM902S1	2JM902S2	2JM902S6	2JM902S7	2JM902S8	2JM902S9	2JM902SA
			2JM902T2	2JM902T3	2JM902T4	2JM902T5	2JM902T6	2JM902T7	2JM902U1	2JM902U2
			2JM902U3	2JM902U4	2JM902U5	2JM902U7	2JM902U9	2JM902UA	2JM902V1	2JM902V2
			2JM902W2	2LM900F1	2LM900F2	2LM900F4	2MM90071	2MM90072		
	ES839	33	2FM905Q1	2FM905T6	2FM905T7	2FM905T8	2FM905T9	2FM905TA	2GM906C1	2GM906C2
			2GM906C3	2GM906C4	2GM906C5	2GM906C6	2GM906H1	2GM906H2	2GM906H3	2GM906H4
			2GM906H6	2GM906H7	2HM905E8	2HM905EA	2JM902E1	2JM902E2	2JM902E3	2JM902E4
			2JM902E5	2JM902E6	2JM902H1	2JM902H2	2JM902H3	2JM902Q1	2JM902Q4	2JM902Q5
			2JM902Q7							

HOYA Vivinex Toric XY1A Total 3823
Total no. of affected products in India 3823 Units

Prepared by:
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Hoya Medical India Pvt Ltd

Praveen
28-April-2023



Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Notification

HOYA Vivinex iSert Toric IOLs

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Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.
- More information about Australian recall actions is available at <http://tga.gov.au/safety/recalls-about.htm>
- If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <http://www.healthdirect.org.au/>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

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Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2023-RN-00323-1
Product Name/Description ⁱⁱⁱ	HOYA Vivinex iSert Toric IOLs Model numbers: XY1AT2, XY1AT3, XY1AT4, XY1AT5, XY1AT6, XY1AT7, XY1AT8 and XY1AT9 Manufactured from June 2022 to January 2023 ARTG 287542 (Designs for Vision Aust Pty Ltd - Lens, intraocular, posterior chamber)
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	12/04/2023
Responsible Entity ^{vii}	Designs for Vision Aust Pty Ltd
Reason / Issue ^{viii}	HOYA Surgical Optics is recalling HOYA Vivinex iSert Toric IOLs from a specified manufacturing period (June 2022 to January 2023) and have received customers complaints in Australia and Japan, with reports of damage (such as scratches) and fragment adhesion on the IOL optic surface. Following the initial investigation of returned samples, HOYA identified that damage had occurred to the nozzle tip of the iSert injector during Toric IOL implantation. This damage might have led to the reported scratches on the optic surface and polypropylene (PP) resin fragments from inside the injector tip to adhere to the IOL surface (PP adhesion).
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	HOYA Surgical Optics ask customers to place all impacted devices on hold in their inventory system and quarantine them for collection by a Designs For Vision representative. HOYA Surgical Optics notes that IOL explantation is not recommended, however it is recommended that the patients involved, i.e., the cases where lenses with PP adhesion have been left in the eye, be monitored for the need for any future medical treatment.
Contact Information ^{xi}	1800 225 307 - Designs For Vision

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch /

serial numbers.

iv Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

v Recall Action Classification**: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

vi Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

vii Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

viii Reason / Issue: Reason for the recall action.

ix Recall Action**: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

x Recall Action Instructions: What customers with affected goods should do.

xi Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:

<https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf>