

For Presentation to the Authorities

Declaration of Non-IVD Products

June 24, 2020

To Whom It May Concern,

We,

Ventana Medical Systems, Inc.
1910 East Innovation Park Drive
Tucson, AZ, 85755
United States

herewith confirm that the products listed in the attachment are not categorized as IVD products according to IVD Directive 98/79/EC. These non-IVD products do not require/have any documentations, including the EC Declaration of Conformity.

Sincerely,

Ventana Medical System, Inc.
A Member of the Roche Group



Ellen Hong, R.A.C.
Sr. Regulatory Affairs Specialist

Attachment

	Material No	Product Description
1	05244676001	BOTTLE, 20 LITER GRADUATED
2	05247829001	Label, Blank, Flap, 540 Roll
3	05248850001	KIT PACK, EBAR (US/EUROPE)
4	05250862001	ASSY, EBAR PRINTER
5	05250889001	RIBBON, EBAR PRINTER
6	05250986001	ASSY, WASTE CONTAINER AND CART
7	05253560001	ASSY, REAG. TRAY W. MAGNET, BMK/DISCOVERY/IH
8	05260132001	Cable, Ethernet, Cat5e
9	05260833001	Brush, Coverslipper Unload Channel
10	05263212001	CORD, AC POWER INTL, CONT. EURO.
11	05264898001	NEXES COMPUTER SYSTEM, 100-230V
12	05266017001	ACCESSORY KIT
13	05287693001	Multi-plug, 6-pos, Continental
14	05342724001	Ventana BenchMark Ultra Computer System,
15	05424577001	Kit, Accessory no.2, BenchMark Ultra
16	05424585001	BenchMark Ultra Kit Assy no.1
17	05865379001	BENCHMARK GX BOTTLE SHIP KIT RAISED ACC
18	05894689001	BENCHMARK GX DRAWER (Assy)
19	06449883001	PC ASSEMBLY, VENTANA HE 600
20	06563716001	REAGENT TRAY, BMK SPECIAL STAINS
21	06563724001	BOTTLE SHIP KIT, BMK SPECIAL STAINS
22	06564909001	ACCESSORY KIT, BMK SPECIAL STAINS
23	06720269001	1D Barcode Activation Key
24	06720277001	2D DATAMATRIX - Barcode Activation Key
25	06720285001	2D PDF417 - Barcode Activation Key
26	06947085001	LYSOL IC DECON SOLUTION 1 GAL
27	07358288001	VENTANA HE 600 INSTALL KIT SLIDES
28	07358822001	VENTANA HE 600 System Waste Module
29	07496338001	VENTANA HE 600 Bottle Hat 1 (WHT, 4L)
30	07496346001	VENTANA HE 600 Bottle Hat 3 (BLU, 2L)
31	07496354001	VENTANA HE 600 Bottle Hat 4 (PNK, 2L)
32	07496362001	VENTANA HE 600 Bottle Hat 5 (GRY, 2L)
33	07496389001	VENTANA HE 600 Bottle Hat 6 (YLW, 2L)
34	07496397001	VENTANA HE 600 Bottle Hat 7 (TAN, 2L)
35	07496419001	VENTANA HE 600 Bottle Hat 8 (GRN, 2L)

	Material No	Product Description
36	07496427001	VENTANA HE 600 System Slide Tray - 25mm
37	07496435001	VENTANA HE 600 System Slide Tray - 26mm
38	07496443001	VENTANA HE 600 System Waste Carboy
39	07496478001	VENTANA HE 600 System Keyboard
40	07496494001	VENTANA HE 600 Air Filter 6 in. sq.
41	07496508001	VENTANA HE 600 System Stainer Module
42	07496516001	VENTANA HE 600 System Coverslipper Mod
43	07524994001	HE 600 PM Reagent Kit
44	07676727001	VENTANA HE 600 Bottle Hat 2 (PPL, 2L)
45	07788746001	WASTE ASSY, DIR TO DRAIN, VENTANA HE 600
46	07788762001	POWER CORD, VENTANA HE 600
47	07797877001	MANUAL TRAY REMOVAL KIT, VENTANA HE 600
48	07801700001	SITE PREP & EXHAUST KIT, VENTANA HE 600
49	07816421001	COMPUTER MONITOR ARM
50	07820623001	SEISMIC KIT, VENTANA HE 600
51	07867875001	MODULE LIFT VENTANA HE 600
52	05260922001	H-Seal, FKM, 65 Durometer
53	07988206001	PCBA SLIDE CAROUSEL GX SVC