



DEVICE DETAILS

NAME OF DEVICE	DAKO PRIMARY ANTIBODIES (KIDNEY AND URINARY TRACT)
ESTABLISHMENT NAME	BITA LIFESCIENCE SDN. BHD.
REGISTRATION NO	IVDC17498297018
BRAND NAME	DAKO
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	PRIMARY ANTIBODIES ARE INTENDED FOR USE ON TISSUE SECTIONS.
DEVICE INTENDED PURPOSE	FOR IN VITRO DIAGNOSTIC USE. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.
VALIDITY DATE OF REGISTRATION	26/09/2018 - 25/09/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FLEX Monoclonal Mouse Anti-Human Vimentin, Clone V9, Ready-to-Use (Link)	IR630
2	FLEX Monoclonal Mouse Anti-Vimentin, Clone V9, Ready-to-Use (Dako Omnis)	GA630
3	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4, Ready-to-Use (Dako Autostainer/Autostainer Plus)	IS611
4	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4, Ready-to-Use (Link)	IR611
5	Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4	M0851
6	FLEX Polyclonal Rabbit Anti-S100, Ready-to-Use (Dako Autostainer/Autostainer Plus)	IS504
7	FLEX Polyclonal Rabbit Anti-S100, Ready-to-Use (Link)	IR504
8	FLEX Polyclonal Rabbit Anti-S100, Ready-to-Use (Dako Omnis)	GA504
9	FLEX Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314, Ready-to-use (Dako Autostainer/Autostainer Plus)	IS075
10	FLEX Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314, Ready-to-use (link)	IR075

NO	NAME OF DEVICE	IDENTIFIER
11	Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314	M3632
12	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1, Ready-to-Use (Dako Autostainer/Autostainer Plus)	IS626
13	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1, Ready-to-Use (Link)	IR626
14	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1, Ready-to-Use (Dako Omnis)	GA626
15	FLEX Monoclonal Mouse Anti-Vimentin, Clone V9, Ready-to-Use (Dako Autostainer/Autostainer Plus)	IS630

