



DEVICE DETAILS

NAME OF DEVICE	VITASCAN PD+ BLADDER SCANNER
ESTABLISHMENT NAME	ATALIS HEALTHCARE SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB8210921-73318
BRAND NAME	VITASCAN
MEDICAL DEVICE CATEGORY	MD 1200 - DEVICES FOR IMAGING
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	VitaScan PD+ bladder scanner is a B-mode ultrasound instrument, portable and battery operated. A mechanical sector scanning transducer provides cross-sectional images of the bladder and based on these images the scanner automatically calculates the estimated bladder volume and displays it on screen. It is a safe and easy, non-invasive method to measure bladder volume.
DEVICE INTENDED PURPOSE	VitaScan PD+ bladder scanner intended for the non-invasive measurement of urinary bladder volume.
VALIDITY DATE OF REGISTRATION	20/09/2021 - 19/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	VitaScan PD+ Console with printer	100580
2	VitaScan PD+ Bladder Scanner	100580 CP
3	VitaScan PD+ Bladder Scanner with VitaScan Mobile Cart	100580 MP
4	Optional accessories	Null
5	Vesa mount Bracket with adhesive tape	100766
6	Universal Tablet Holder with key lock for VitaScan Mobile Cart	100763
7	Power adaptor Holder for VitaScan Mobile Cart	100767
8	VitaScan v.2 soft carrying case	100561
9	VitaScan v.2 probe sleeve	100681
10	VitaScan probe brace for Vitascan Mobile Cart	100682
11	Plate for laptop- VESA mount	100543

NO	NAME OF DEVICE	IDENTIFIER
12	VitaScan PD Soft Carrying Case	100560
13	VitaScan Verification Test Tool v.2 probe	100751
14	VitaScan LT probe replacement	100664
15	VitaScan v.2 probe replacement	100665
16	VitaScan PD Printer Paper	100586
17	Custom My Printer	100950
18	VitaScan Mobile Cart	100762
19	VitaScan Calibration Test Tool	100651
20	VitaScan Verification Test Tool	100752



MEDICAL DEVICE AUTHORITY