

Declaration of Conformity

In accordance with Annex II Clause 3 of the MDD 93/42/EEC

Manufacturer: UAB VITACON LT
Address: Naujoji g.12-525.
Alitaus 62401
Lithuania

PRODUCT:
Type/Model: VitaScan LT USB Ultrasound Bladder
Description: Unique non-invasive system for automatic bladder volume measurement.
Classification: Ila

Name of Medical Device		VitaScan LT USB Ultrasound Bladder Monitor
Name as per Device Label	Identifier (Item Code)	Brief Description of Item
VitaScan LT Bladder Scanner - USB probe	100525	The VitaScan LT is a B-mode ultrasonic instrument, which projects ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder, which is used to determine bladder volume non-invasively, on an intermittent basis. Including: USB probe, Probe Sleeve, VitaScan LT software (on memory stick), Digital documentation, Soft Carrying Case and Calibration certificate. Software version: VitaScan_LT_SW001 Version 3.01.
VitaScan LT Bladder Scanner - Medical grade system with VitaScan Mobile Cart	100525 ML	Including: VitaScan LT Bladder Scanner - USB probe, Vitacon LAMINA medical grade Tablet with preinstalled VitaScan LT software and preinstalled user-video, Vesa mount Bracket with adhesive tape, VitaScan Mobile Cart with adjustable height, VitaScan Probe Sleeve, Probe Brace and Basket with handle, Digital documentation. Software version: VitaScan_LT_SW001 Version 3.01.
VitaScan LT - Wi-Fi Module	100697	Including: 2A@5V charger, USB cable
VitaScan Mobile Cart	100762	VitaScan Mobile Cart with adjustable height, Probe Brace and Basket with handle

Vitacon LAMINA Tablet	100764	Vitacon LAMINA Tablet, Quad-Core Intel® processor, Windows® operating system, preinstalled VitaScan LT Software and 10.1" display
VitaScan Probe Sleeve	100680	ABS plastic VitaScan probe sleeve to hold the VitaScan LT Bladder Scanner probe. Can be fixed on a table or a roller stand brace.
Custom My printer	100950	Custom My printer - Bluetooth thermal printer - 57 mm paper width
VitaScan Calibration Test Tool	100651	Test Tool to perform VitaScan LT on-site calibration
VitaScan Verification Test Tool	100752	Test Tool to perform VitaScan LT on-site verification

We herewith declare that above mentioned product meet the transposition into national law of the provisions of council directive MDD 93/42/EEC

UAB VITACON LT

Date: 02nd of May, 2017

Signature: 
Svein Wognild

VITACON.