DECLARATION OF CONFORMITY

Manufacturer:

Verathon Inc.
20001 North Creek Pkwy
Bothell, WA 98011
USA

European Authorized Representative:

Verathon Medical Europe B.V.
Willem Fenengastraat 13
1096 BL Amsterdam
The Netherlands

Product:

BladderScan i10™ System, International, 0270-1015
BladderScan i10™ Console, 0570-0412
BladderScan i10™ Probe, 0570-0413
BladderScan i10™ Probe only, 0270-1019
BladderScan i10™ System, US, 0270-1014
BladderScan i10™ System, ANZ, 0270-1017

Classification/Rule: Class IIa, Rule 10

Conformity Assessment Route: Annex II excluding 4

GMDN Code and Term:

40761-Ultrasound system, imaging, general-purpose

We, Verathon Inc., herewith declare under our sole responsibility that the products listed above meet the provisions of Council Directive 93/42/EEC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:

TÜV SÜD Product Service GmbH (ID. No. 0123)
Ridlerstaße 65
80339 München
Germany

Standards Applied:

EN ISO 13485: 2016	Quality Management Systems. Medical Devices.
EN ISO 14971: 2012	Medical Devices. Application of Risk Management to Medical Devices.
EN 60601-1:2006/A1:2013	Medical Electrical Equipment. Part 1: General Requirements for Basic Safety and Essential Performance.
EN 60601-1-6:2010/A1:2013	Medical Electrical Equipment. Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
EN 62366-1:2015	Medical Devices. Application of Usability Engineering to Medical Devices.
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied. Part 1: General Requirements.
EN 60601-2-37:2008/A1:2015	Medical Electrical Equipment. Part 2-37: Particular Requirements for the Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment.
EN 60601-1-2:2015	Medical Electrical Equipment. Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests.
EN ISO 10993-1:2020	Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing.
EN ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of medical devices-part 10: Tests for irritation and skin sensitization
EN ISO 10993-12:2012	Biological evaluation of medical devices- Part 12: Sample preparation and reference materials.
ISTA 2A:2011	Standard Practice for Performance testing of Shipping Containers and Systems.
MEDDEV 2.7/1 Rev. 4 (June 2016)	Guidelines on Medical Devices; Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
AAMI TIR12: 2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
EN 62304: 2006/ A1:2015	Medical Devices Software – Software Life cycle Processes
EN 60529:1991/A1:2000/A2:2013	Degrees of Protection by enclosures (IP Code)
EN ISO 17664: 2017	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Devices that require cleaning followed by disinfection and/or sterilization.

IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
NEMA UD 2-2004 (R2009)	Acoustic output measurement standard for diagnostic ultrasound equipment.
NEMA UD 3-2004	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2
IEC 62359: 2010/A1: 2017	Ultrasonics – Field Characterization-Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
IEC 61161: 2013	Ultrasonics. Power measurement. Radiation force balances and performance requirements

The CE marked product was evaluated with the following accessories:

- Battery, Li-Ion, 6400mAh, 10.1V, 71Wh, 0400-0155
- BladderScan i10 Power adapter, 0400-0156
- USB cable, Type A Male to B Male, 6ft, Printer, Odin, 0800-0639
- Thermal printer paper, 0800-0319
- BladderScan i10 In-service USB, 0901-6346
- BladderScan i10 Workstation, 0800-0631
- BladderScan i10 Printer Kit, 0800-0640
- BladderScan i10 Printer, 0800-0632
- Line cord, EU, 0600-0600
- Line cord, UK, 0600-0712
- Line Cord, Denmark, 0600-0815
- Line cord, Switzerland, 0600-0816
- Line Cord, Australia, 0600-0734
- Ultrasound Gel, 8.5oz, Aquasonic 100, Box of 12 (EMEA single bottle), 0800-0005
- Ultrasound Gel, 20g, Single Use Packette, Aquasonic 100, 100 Per Box, 0800-0643
- Calibration Tank kit, 0620-1083
- BladderScan® Smart Battery Charger, 0400-0157
- Barcode Scanner Kit, BladderScan i10, 0810-0291

Separately CE Marked accessories include:

- BladderScan® Smart Battery Charger, 0400-0157
- Ultrasound Gel, 0800-0005
- Thermal printer paper, 0800-0319
- BladderScan i10 Workstation, 0800-0631

- Calibration Tank kit, 0620-1083
- Barcode Scanner Kit, BladderScan i10, 0810-0291

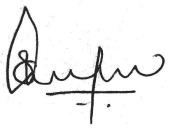
EC Certificate Number: G1 061293 0026 Rev. 00

Date of Original CE Mark: 2021-05-06

Place of Issue: Bothell, WA, 98011 USA

Name of Authorized Signatory/Title:

Swapna Chirala
Manager, Regulatory Compliance

Signature: 

Date: 03-March-2022