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
Netherlands

Product:

BVI 6x00 Calibration Phantom, 0620-0225
BladderScan® BVI 9400 Calibration Phantom, 0620-0340
BladderScan® Pediatric Phantom, 0620-0273
BladderScan® Tissue Equivalent Phantom, 0620-0068
BladderScan® Tissue Equivalent Phantom for Demonstration and Training, 0620-0274
BladderScan® Prime Calibration Tank, 0620-0739
BVI 6100, Calibration and Support System, 0270-0790
BVI 6400, Calibration and Support System, 0270-0793
BladderScan i10 Calibration Tank, 0620-1083

Classification/Rule: Class 1, Rule 1

Conformity Assessment Route: Annex II excluding 4

GMDN Code and Term:

40628 – Diagnostic, Ultrasound Phantom, Test object

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.

Date of Original CE Mark: 2016-08-12

Place of Issue: Bothell, WA, 98011 USA

Name of Authorized Signatory/Title:

Teresa M Davidson
Director, Regulatory Affairs

Signature: 

Date: 06-May-2021