



DECLARATION OF CONFORMITY

In accordance with Annex VII Clause 3 of the Medical Device Directive (93/42/EEC)

declares that the product:

Product Name: FloPoint Elite Uroflowmeter
Model Number(s): 0570-0175, 0570-0174, 0570-0176
Options: N/A
Date CE Mark was affixed: February 15, 2008

Classification: I Rule: I

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of council directive 93/42/EEC for medical devices. Verathon Medical, Bothell, WA, USA is Annex II.3 certified, certificate number G1 07 11 61293 006.

Notified Body: TUV PRODUCT SERVICE GMBH, Ridlerstrasse 65, D-80339, Munchen, Germany

The Quality Management System under which the product is manufactured meets the requirements of ISO13485:2003.

Date: 02/12/10

Director, QA/RA

For Standards References refer to the following documents:
Technical File: 0004-0092-xx-99
Essential Requirements Checklist: 0004-0238-xx-ERC

Authorized Representative
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