CE 0123

DECLARATION OF CONFORMITY

PHILIPS

Philips Medical Systems
3000 Minuteman Road
Andover, MA. 01810-1099
USA

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name: IntelliVue Information Center Application Software for M3140, M3145, M3150, M3151, M3154, M3155, M3169, M3170 and M3177

Product Model Number or Designator: M3290A

Control Indicator: N.01

Device Classification per specified directive: Class IIb, rule 10

Global Medical Device Nomenclature Code (GMDN) and Title: 38470

Product Options/Accessories: As described in the Instructions For Use.

The object of the declaration described above is in conformity with:

- **Council Directive 93/42/EEC concerning medical devices**

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 3.2 of the Medical Device Directive. Copies of the Quality System certificates are available upon request.

Name/Address of Notified Body: TUV SUD Product Service GmbH / TÜV SÜD Product Service GmbH Ridlerstraße 65; 80339 MÜNCHEN; Germany

Authorized EU Representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany

Supplementary Information:

The software has been verified compatible and is suitable for use with the IntelliVue M3140, M3145, M3150, M3151, M3154, M3155, M3169, M3170 and M3177, as well as the M3160 & M3176B/C recorders, as described in accompanying documents.

Signature (signed for and on behalf of Philips):

Date of Issue: 04-SEP-2014

Printed Name: Tom Fallon

Place of Issue: Andover

Title: Director, Quality and Regulatory Affairs