

EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Address: 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto
615-0084 JAPAN

European Representative: OMRON HEALTHCARE EUROPE B.V.
Address: Kruisweg 577, 2132 NA Hoofddorp, The Netherlands

Product: Printer HEM·PRT1·E
Model: HHX·PRINT·E1 (HEM·PRT1·E)
MDD Classification: Class I
(MDD Annex IX Rule1)

We herewith declare that the above mentioned product meets the provisions of the following European Committee Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer and the notified body.

Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC

Standards: EN 60601-1:1990+A1:1993+A2:1995
EN 60601-1-2:2007
EN 980:2008
EN 1041:2008
EN ISO 14971:2007
EN 62366:2008

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nuremberg, Germany
Notified under number 0197 to the EC Commission

Certificate: Annex II: HD 60018171 0001

Place / Date: Kyoto, Japan / March 29, 2010

Signature:

Name: 
Norikazu Yasue

Position: General Manager
Customer Satisfaction Management Division
OMRON HEALTHCARE Co., Ltd.