

EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
 Address: 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN
 European Representative: OMRON HEALTHCARE EUROPE B.V.
 Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands
 Product Category: Electrocardiographic Intermittent Event Recorders
 Model (code): HCG-801(HCG-801-E)
 Classification for MDD: Class IIa(MDD Annex IX Rule 10)
 Product Category for RoHS: Category 8 (Medical devices)

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.
 This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

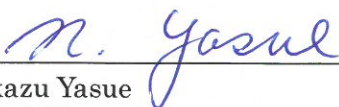
Directives

General applicable directives:	Relevant regulations and harmonized standards
93/42/EEC Medical Device Directive (MDD)	EN 980:2008 EN 1041:2008 EN 60601-1:1990+A1:1993+A2:1995 EN 60601-1-2:2007 EN 60601-1-4:1996+A1:1999 EN 60601-1-6:2004 EN 60601-2-47:2001 EN 62304:2006 EN 62366:2008 EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN ISO 14971:2012
2011/65/EU Restriction of Hazardous Substances (RoHS)	EN50581:2012

Notified Body: TÜV Rheinland LGA Products GmbH
 Address: Tillystrasse 2, 90431 Nuremberg, Germany
 ID No: Notified under number 0197 to the EC Commission
 Certificate Registration No: Annex V : DD 60100204 0001

Place / Date: Kyoto / March 25, 2016

Signature:


 Name: Norikazu Yasue
 Position: General Manager
 Customer Satisfaction Management Division