

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: Electroanalgesic Transcutaneous Stimulators
Product Description: Pain Reliever
Model (code): E3 Intense(HV-F021-EW)
Classification for MDD: Class IIa(MDD Annex IX Rule 9)
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.

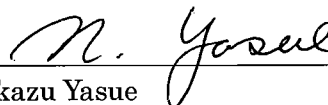
Directives

General applicable directives:	Relevant regulations and harmonized standards
93/42/EEC Medical Device Directive (MDD)	EN980:2008 EN1041:2008 EN 60601-1:2006+A1:2013 EN60601-1-2 :2007 EN60601-1-6:2010 EN60601-1-11:2010 EN60601-2-10 :2015 EN62304:2006 EN62366:2008 EN ISO10993-1 :2009 EN ISO10993-5 :2009 EN ISO10993-10 :2010 EN ISO14971:2012
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 II : HD 60100203 0001

Place / Date: Kyoto / July 24, 2015

Signature:



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