OMRON

No: OHQ(CS)-DOC-110228G

# EC Declaration of Conformity

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| 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 Stimulation Electrodes |
| Model (code): | Long Life Pads(HV-LLPAD-E) |
| Classification: | Class IIa(MDD Annex IX Rule 9) |

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

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| General applicable directives: | 93/42/EEC Medical Device Directive (MDD) |
| Standards: | EN 980:2008<br>EN 1041:2008<br>EN ISO 10993-1:2009<br>EN ISO 10993-5:2009<br>EN ISO 10993-10:2009<br>EN ISO 14971:2009 |
| 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 / September 1, 2015 |
| Signature: | |
| Name: | Norikazu Yasue |
| Position: | General Manager<br>Customer Satisfaction Management Division |