OMRON

No: OHQ(CS)-DoC(MDD)-9912905C

# 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: | Ear Thermometers |
| Model Name(-code): | Gentle Temp 522 PRO(MC-522-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 |
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| 93/42/EEC Medical Device Directive (MDD) | EN ISO15223-1:2012<br>EN980 :2008<br>EN1041:2008<br>EN60601-1:2006<br>EN60601-1-2:2007<br>EN60601-1-6:2010<br>EN ISO14971:2012<br>EN ISO10993-1:2009<br>EN ISO10993-5:2009<br>EN ISO10993-10:2010<br>EN62304:2006<br>EN62366:2008<br>EN12470-5:2003<br>EN60601-1-11:2010<br>EN ISO80601-2-56 :2012 |
| 2011/65/EU Restriction of Hazardous Substances (RoHS) | EN50581:2012 |

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| 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 / May 29, 2015 |
| Signature: | N. Yasue |
| Name: | Norikazu Yasue |
| Position: | General Manager<br>Customer Satisfaction Management Division |