

## EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.  
Single Registration Number: JP-MF-000007213  
Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN  
European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.  
Single Registration Number: NL-AR-000002683  
Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands  
Product Category: Ear Thermometers  
Model (code): Gentle Temp 521 (MC-521-E)  
Basic UDI-DI: 4015672107805R  
MDR Classification: Class IIa (MDR Annex VIII Rule 10)

We herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer and the European Authorized Representative.

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

General applicable regulations:	Medical Device Regulation (EU) 2017/745
Standards:	EN 1041:2008+A1:2013      EN ISO 10993-1:2020 EN 12470-5:2003      EN ISO 10993-5:2009 EN 60601-1:2006+A1:2013      EN ISO 10993-10:2013 EN 60601-1-2:2015      EN ISO 13485:2016 EN 60601-1-6:2010+A1:2015      EN ISO 14971:2019 EN 60601-1-11:2015      EN ISO 15223-1:2016 EN 62304:2006+A1:2015      EN ISO 80601-2-56:2017 +A1:2020 EN 62366-1:2015 +A1:2020
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 IX : HZ 2102042-1

General applicable directives:	RoHS Directive 2011/65/EU, (EU)2015/863 and (EU)2017/2102
Product Category for RoHS:	Category 8 (Medical devices)
Standards:	EN IEC 63000:2018

Place / Date: Kyoto / February 15, 2023

Signature:

Name:   
Position: Takefumi Nakamishi  
General Manager  
Regulatory Affairs Department



Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9067039

Intended purpose of the model:

The OMRON Gentle Temp 521 offers comfortable, safe, accurate and quick temperature measurement from the eardrum. Designed to be used on people of all ages.