

## 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: Electroanalgesic Transcutaneous Stimulators  
Model (code): E3 Intense (HV-F021-ESL)  
Basic UDI-DI: 4015672109535Y  
MDR Classification: Class IIa (MDR Annex VIII Rule 9)

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 60601-1:2006+A1:2013      EN ISO 10993-5:2009 EN 60601-1-2:2015      EN ISO 10993-10:2013 EN 60601-1-6:2010+A1:2015      EN ISO 13485:2016 EN 60601-1-11:2010      EN ISO 14971:2019 EN 60601-2-10:2015      EN ISO 15223-1:2016 EN 62304:2006+A1:2015 EN 62366-1:2015

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 28, 2023

Signature:

  
Name: Takefumi Nakahishi  
Position: General Manager  
Regulatory Affairs Department

Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9702151

**Intended purpose of the model:**

OMRON E3 Intense is a Pain Reliever intended for reducing and relieving muscles and joints pain, stiffness and numbness in the back, arms, legs, shoulders and feet by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It should be applied to normal, healthy, dry, and clean skin of adult patients.