No: OHQ(CS)-DoC(MDD)-9702151E

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
Model (code) :	E3 Intense (HV-F021-ESL)
Classification for MDD:	Class IIa (MDD Article 9 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 at 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)	EN ISO 15223-1:2016 EN 1041:2008 EN 60601-1:2006+A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-11:2010 EN 60601-2-10:2015 EN 62304:2006+A1:2015 EN 62366:2008 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 14971:2012
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 60100990 0001
Place / Date:	Kyoto / March 29, 2019
Signature:	
Name:	Takefumi Nakanishi
Position:	General Manager Regulatory Affairs Department