No: OHQ(CS)-DoC(MDR)-3147329

EU 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:	Wegalaan 73, 2132 JD Hoofddorp, THE NETHERLANDS
Product Category:	Electroanalgesic Transcutaneous Stimulators
Model (code):	E3 Intense (HV-F021-E4W)
Basic UDI-DI:	4015672 11356 5F
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 60601-1:2006+A1:2013	EN ISO 10993-1:2020
	EN 60601-1-2:2015	EN ISO 10993-5:2009
	EN 60601-1-6:2010+A1:2015	EN ISO 10993-10:2013
	EN 60601-1-11:2015	EN ISO 13485:2016
	EN 60601-2-10:2015+A1:2016	EN ISO 14971:2019
	EN 62304:2006+A1:2015	EN ISO 15223-1:2021
	EN 62366-1:2015	EN ISO 20417:2021
Notified Body:	TÜV Rheinland LGA Products GmbH	
Address:	Tillystraße 2, 90431 Nürnberg, 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 / April 19, 2024

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

Attachment to EU Declaration of Conformity No. OHQ(CS)-DoC(MDR)-3147329

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.

OMRON HEALTHCARE Co., Ltd.
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