

Declaration of Conformity

Manufacturer: MINATO MEDICAL SCIENCE CO., LTD Kobe Facility
5-2-10, Minatojima-Minamimachi, Chuoh-ku, Kobe-shi,
Hyogo, 650-0047, JAPAN

Product: Physical Therapy Massager

Trade Name AQUATIZER QZ-240SG SN 70001~

Classification (MDD, Annex IX): Class IIa

Classification Rule: Rule 9

UNDNS code: 15662

Conformity Assessment Route Requested: Annex II excluding (4)

I, the undersigned, herewith declare that the above-mentioned product(s) meet the provisions of the following EC Council Directives and harmonized standards. All Supporting documentations are retained under the premises of the manufacturer and the notified body. The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives: EC DIRECTIVE: Medical Devices Directive

(MDD 93/42/EEC as amended according to the
Directive 2007/47/EC)

Standard: All applicable harmonized Standard

(EN ISO 13485:2012, EN ISO 14971:2012,
EN ISO 10993-1:2009 / AC2010, EN 1041: 2008,
EN ISO 15223-1:2016 EN 62366: 2008,
EN 60601-1-6: 2010, EN 60601-1:2006/A1:2013,
EN 60601-1-2:2007, EN 62304:2006)

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München Germany

Place: Kobe

Date : 2 - Mar - 2018

Signature: Y. Watanabe

Full Name: Yusuke Watanabe

Position: Manager of Technical law