

Declaration of Conformity

We,

OMRON HEALTHCARE Co., Ltd.,
24 Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto 615-0084 Japan,

as a manufacturer from 1 May, 2004, declare in sole responsibility that the medical device products,

Electronic Digital Fever Thermometer
Flex Temp Smart (MC-343F-E)
(OMRON internal model name:MC-343F-E)

to which this declaration relates is in conformity with the determination of the Council of the European Communities on the Council Directive 93/42/EEC of 14 June 1993 concerning medical device.

The product is classified as **Class IIa** in accordance with Annex IX, rule 10 and complies with Annex I, essential requirements of the Council Directive 93/42/EEC on Medical Devices.

This declaration is based on the Approval in accordance with

Annex II, The Council Directive 93/42/EEC on Medical Devices (Section 4 excepted),
Approval Registration No.: HD 60018171 0001,
Dated on: 16 June, 2008

granted by the Notified Body,

TÜV Rheinland Product Safety GmbH,
Am Grauen Stein D-51105 Köln,
notified under number 0197 to the EC Commission.

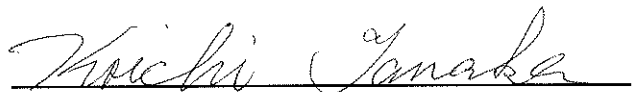
This declaration of conformity is in correspondence to the harmonized standard,

EN 60601-1:1990+A1:1993+A2:1995, EN 60601-1-2:2007, EN60601-1-6:2004,
EN 12470-3:2000, EN980:2008, EN 1041:1998, EN ISO 14971:2000+A1:2003,
EN ISO 10993-1:2003, EN ISO 10993-5:1999, EN ISO 10993-10:2002+A1:2006
EN ISO 10993-12:2004

Ranging from November, 2009 to October, 2011

10 July, 2009

OMRON HEALTHCARE Co., Ltd.



Koichi Tanaka
General Manager,
Customer Satisfaction Management Division