

Head Office

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
Telephone: 81-3-3374-8111 Facsimile: 81-3-3374-8399

Rev.1

DECLARATION of CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo151-0072 JAPAN

declare under our sole responsibility that the product:

Product : Glucose Meter self-testing

Model/Type : MEDISAFE FIT Blood Glucose Meter

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (2014/53/EU).
The product is in conformity with the following standards:

**RADIO : EN 302 291-1 V1.1.1:2005-07
EN 302 291-2 V1.1.1:2005-07**

**EMC : EN 301 489-1 V1.9.2:2011-09
EN 301 489-3 V1.6.1 :2013-08
IEC 61326-2-6:2012
IEC 61326-1:2012**

**SAFETY : EN 50364:2010
EN 61010-2-101:2002
IEC 61010-2-101:2002
IEC 61010-1:2010/Cor.1:2011**



Date : June 9, 2017

Signature : 

Name : Toshio Nakashima

Title : General Manager, Quality Assurance Department

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Object of the declaration

MS 2 FR 5 6 7
 1 2 3 4 5 6 7

No.	Item	Description
1	Product family (item) [2 digits]	MS : MEDISAFE
2	Intended market [1 digit]	* : For outside Japan
3	Product [2 digits]	FR: FIT READER
4	Model number [3 digits]	201: MEDISAFE FIT Blood Glucose Meter
5	Color [1 digit]	B: Blue P: Pink
6	Language [1 digit]	A: English E: Arabic C: Chinese D: German T: Italian
7	Other specifications	1: unit "mg/dL" Blank: unit "mmol/L"