

**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 Smile 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

**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

**Object of the declaration**

MS        FR                  
 1        2        3        4        5        6        7

| No. | Item                                | Description                                 |
|-----|-------------------------------------|---|
| 1   | Product family (item)<br>[2 digits] | MS : MEDISAFE                               |
| 2   | Intended market<br>[1 digit]        | * : For outside Japan                       |
| 3   | Product [2 digits]                  | FR: FIT READER                              |
| 4   | Model number<br>[3 digits]          | 501: MEDISAFE Fit Smile Blood Glucose Meter |
| 5   | Color [1 digit]                     | W: White                                    |
| 6   | Language [1 digit]                  | M: Asia Multi<br>D: German<br>T: Italian    |
| 7   | Other specifications                | 1: unit "mg/dL"<br>Blank: unit "mmol/L"     |