

## **DECLARATION OF CONFORMITY**

**We, TERUMO CORPORATION**

**44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan**

being the manufacturer of:

### **Blood Collection Scale**

**Product : Accessory Related to Blood bags**

declare that the above products of **Class I with a measuring function** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 5 of the Directive, relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" and by certification of Annex V limited to the aspects of the manufacture concerned with the conformity of the products with the metrological requirements, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: DD 60121892 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, August 30, 2017

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

## Appendix A - List of Code Number Structure

## \* Description of product code system

<Product code>	<u>M</u>	<u>E</u>	<u>□</u>	<u>A</u>	<u>C</u>	<u>S</u>	<u>1</u>	<u>0</u>	<u>1</u>
	1	2				3			

## 1. Product group (product item) [two digits]

ME: MEDICAL ELECTRONICS

## 2. Destination (domestic or overseas) [one digit]

- : For domestic      \* : For overseas

## 3. Product category

ACS101: Specific number for TERUMO Blood Collection Scale