

March 2015

To Whom It May Concern:

DECLARATION

The Terumo BCT TSCD® II Sterile Tubing Welder (product code: ME-SC203AH) is intended for laboratory use to automatically and aseptically connect two functionally closed, internally sterile elements (PVC tubing).

When properly used according to the TSCD II operating instructions (the "Operating Instructions"), the device maintains a sterile system for transferring blood or blood products from one sterile collection container to another.

We certify that a sterile weld is produced if the correct tubing type is used and the specifications and the operating instructions are correctly followed as expressly prescribed in the Operating Instructions.

Sincerely,

Ruth Foster
Director, Regulatory Affairs
Terumo BCT EMEA

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikarostraat 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

Terumo BCT (Asia Pacific) Ltd.
Room 3903-3903A, 39/F
ACE Tower, Windsor House
311 Gloucester Road
Causeway Bay, Hong Kong
Phone: +852.2283.0700
Fax: +852.2576.1311

Terumo BCT Latin America S.A.
La Pampa 1517 – 12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Takanawa Park Tower 13F
20-14, 3-chome,
Higashi Gotanda, Shinagawa-ku,
Tokyo, 141-0022 Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800