

EU Declaration of Conformity

Legal Entity: Terumo BCT, Inc.

Address of Legal Entity: 10811 West Collins Avenue

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USA

Authorized Representative Terumo BCT Europe NV

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Product Name: Terumo Sterile Tubing Welder (TSCD-II)

Product Class: The TSCD-II is classified as active laboratory equipment

covered by the Machinery Directive, the Electromagnetic Compatibility Directives and the Directives on Electrical equipment designed for use within certain voltage limits.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

We hereby declare that the Terumo Sterile Tubing Welder (TSCD-II) catalog number ME-SC203AH, complies with the following European Council Directives:

- European Council Directive 2006/42/EC concerning Machinery
- European Council Directive 2014/30/EU concerning Electromagnetic Compatibility
- European Council Directive 2014/35/EU concerning Electrical equipment designed for use within certain voltage limits

In addition to the following European Standards:

EN 61010-1:2010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements

EN 61010-2-010:2014, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-20: Particular requirements for laboratory centrifuges.

EN 61326-1:2013, Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements

Signed for and on behalf of

Rute Rodrigues

Date (YYYY-MM-DD)

Regulatory Affairs Manager, EMEA

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