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June 4, 2014

TO WHOM IT MAY CONCERN

DECLARATION

We, company TERUMO CORPORATION, Kofu Factory, 1727-1, Tsuiji Arai, Showacho, Nakakoma-gun, Yamanashi 409-3853, Japan, hereby declare that TSCD wafer is a disposable product for the TERUMO Sterile Tubing Welder TSCD-II. The TERUMO Sterile Tubing Welder TSCD-II cannot function without the TSCD wafer.

The TSCD wafers are not powered and therefore not active equipment. This means that they do not require the CE marking.

For TERUMO CORPORATION,

Takumi Uchida

Manager of Quality Assurance Section

Elan Valida

Kofu Factory

Terumo Corporation