

## EU Declaration of Conformity

**Manufacturer:**

TOMEY CORPORATION  
2-11-33 Noritakeshinmachi, Nishi-ku, Nagoya Japan

**European Representative:**

Tomey GmbH  
Wiesbadener Straße 21, 90427 Nürnberg GERMANY

**We declare, under our sole responsibility, that the product:**

**Product:** Topographic Modeling System  
**Model:** TMS-4N

**to which this declaration relates complies with the provisions of following European Directives:**

93/42/EEC as amended by 2007/47/EC — Medical Device Directive  
2011/65/EU as amended by (EU) 2017/2102 — Restriction of Hazardous Substances Directive

**MDD Conformity assessment route:**

Directive 93/42/EEC Annex II

**MDD Classification:**

Class IIa (by 93/42/EEC Annex IX rule 10)

**MDD Notified Body:**

SGS Fimko Ltd., (CE0598)  
Särkiniementie 3 Helsinki, 00211 Finland

**MDD EC Certificate:**

FI19/07002

**Applied Standards:**

MDD

EN ISO 13485:2016  
EN ISO 14971:2012  
EN 60601-1:2006/A1:2013  
EN 60601-1-2:2015  
EN 60601-1-6:2010  
EN ISO 15004-1:2009  
EN ISO 15004-2:2007  
EN ISO 10993-1:2009  
EN 60825-1:2007  
EN 62304:2006  
EN 62366:2008  
EN ISO 15223-1:2016  
EN 1041:2008

RoHS

EN IEC 63000:2018

**CE-marking:** on and after 16 September 2014

**Place:** 2-11-33 Noritakeshinmachi, Nishi-ku, Nagoya Japan

**Date of Issue:** 21 October 2021

**Signature:**

  
Toshiya Moro, Director, Administration Department