

# TOWA MEDICAL INSTRUMENTS CO.,LTD.

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Head office·factory

2, December, 2013

## Declaration of Conformity

We declare, under our solo responsibility, that the products:

Product Name	SHIN-NIPPON Trial Frame
Model No.	TF-3
Classification	Class I

The requirements of Council Directive:

93/42/EEC — concerning medical devices, Annex VII

Applied Harmonized Standards:

EN ISO13485:2003	Quality management systems – system requirement for regulation purpose
EN ISO15004-1:2009	Ophthalmic instruments – Fundamental requirements and test methods
EN ISO12867:1998	Ophthalmic instruments – Trial frames (ISO12867:1998)

Manufacturer's name: TOWA MEDICAL INSTRUMENTS Co., Ltd.

1698-2, Oaza-Nakano, Nakanoshi, Nagano 383-0013, Japan

The authorized signatory to this declaration:

Signature: \_\_\_\_\_



Name: Koichi Kasuya

Position: President