

TOWA MEDICAL INSTRUMENTS CO.,LTD.

Head office・factory: 1698-2, Oaza-Nakano, Nakanoshi, Nagano 383-0013, Japan
Telephone: +81-269-22-5181 Telefax: +81-269-22-5184
Tokyo office: 2-10-10, Yushima, Bunkyo, Tokyo 113-0034, Japan
Telephone: +81-3-3818-4421 Telefax: +81-3-3818-4423



Head office・factory

2, December, 2013

Declaration of Conformity

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

Product Name	SHIN-NIPPON REFRACTOR
Model No.	BR-7
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
ISO 10341:2012	Ophthalmic instruments -- Refractor heads
JIS T7308:2002	Refractor heads

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