



NEITZ INSTRUMENTS CO., LTD.

4F Ichibancho Court, 15-21, Ichibancho, Chiyoda-ku, Tokyo 102-0082, Japan
Phone : (+81) 3-3237-0552 Fax : (+81) 3-3237-0554
URL: <http://www.neitz-ophthalmic.com>

TD14-10750001-02

DECLARATION OF CONFORMITY

Manufacturer: NEITZ INSTRUMENTS CO., LTD.
4F Ichibancho Court, 15-21, Ichibancho, Chiyoda-ku,
Tokyo 102-0082, Japan

European Authorized Representative: Medical Device Safety Service GmbH
Schiffgraben 41, D-30175 Hannover, Germany

Product: Halogen Ophthalmoscopes and Accessories
Product Numbers and Description: as listed in Attachment

Applicable Serial Number: BX α -13: Head: 00103A194 and later Handle: 00505A012 and later
BX α -13A: Head: 00103A194 and later Handle: 00804A017 and later
BX α -RC: Head: 00103A194 and later Handle: 00604A068 and later

Device Classification: Class I

GMDN Classification: 12817

Standards Applied: EN 60601-1:2006/A1:2013
EN 6060-1-2:2007
EN 60601-1-6:2010
EN 62366:2008
EN ISO 14971:2012
DS/EN ISO 13485:2012
EN 980:2008
EN ISO 10993-1:2009/AC:2010
EN ISO 15004-1:2009

We, manufacturer, hereby declare that the above-mentioned products conform to the applicable provisions of the Medical Devices Directive 93/42/EEC.
This declaration of conformity refers to the above-mentioned serial numbers of products.

Date: July 1, 2015

Signature: Takae Nishizawa
Takae Nishizawa, President



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Attachment

Neitz Direct Ophthalmoscopes and Accessories:

Product Number	Product Description	Model Name/Type
101021	Halogen Ophthalmoscope	BX α -13
101041		BX α -13A
101151		BX α -RC
101521	Head Part of BX α	BX α -HEAD
199011	Cord Handle for BX α , RX	α -No. 2
199021	C Cell Battery Handle for BX α , RX	α -No. 3
199031	AA Cell Battery Handle for BX α , RX	α -No. 3A
199041	Rechargeable Handle for BX α , RX	α -No. RC
199071	Rechargeable Plug-in Battery Handle 120V for BX α , RX	α -No. RP 120V
199081	Rechargeable Plug-in Battery Handle 230V for BX α , RX	α -No. RP 230V
199541	Cord for BX α , RX (with Pin-Jack Plug)	Cord C
199551	Cord for BX α , RX (with Banana Plug)	Cord D
199561	Cord for BX α , RX (with Push-Pull Plug)	Cord E
115081	Dual Desk Charger for BX α , RX	RC-II
601280	Halogen Bulb for BX α 4V	L-29
601290	Halogen Bulb for BX α 3V	L-30
601370	Halogen Bulb for GH, a-Jr	L-38