



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>

TD14-12420001-03

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: Binocular Loupe BL Series with BETA, NEO or TITANIUM Frame and
Accessories
Product Numbers and Description: Listed in Attachment

Applicable Serial Number: Listed in Attachment

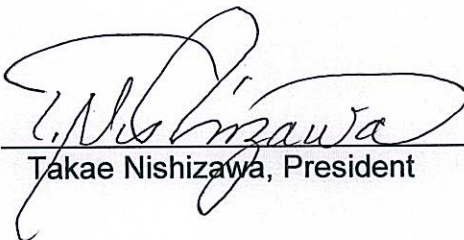
Device Classification: Class I

UMDN Classification: 15652 (Loupe)

Standards Applied: EN 62366:2008
EN ISO 14971:2012
EN ISO 13485:2012
EN 980:2008

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 serial numbers of products mentioned on the Attachment.

Date: Aug 23, 2016

Signature: 
Takae Nishizawa, President



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Attachment

Binocular Loupe BL Series with BETA, NEO or TITANIUM Frame and Accessories:

Product Number	Product Description	Model Name/Type	
131431	Binocular Loupe	BLS-1 BETA (Red)	
131441		BLS-1 BETA (Black)	
131451		BLS-1 BETA (Blue)	
131491		BLS-3 BETA (Red)	
131501		BLS-3 BETA (Black)	
131511		BLS-3 BETA (Blue)	
131551		BLP-4 BETA (Red)	
131561		BLP-4 BETA (Black)	
131571		BLP-4 BETA (Blue)	
131581		BLP-6 BETA (Red)	
131591		BLP-6 BETA (Black)	
131601		BLP-6 BETA (Blue)	
131521		BLD-3 BETA (Red)	
131531		BLD-3 BETA (Black)	
131541		BLD-3 BETA (Blue)	
131461		BLS-2 BETA (Red)	
131471		BLS-2 BETA (Black)	
131481		BLS-2 BETA (Blue)	
143001		Binocular Loupe	BLS-1 NEO (White-Pink)
143011			BLS-1 NEO (White-Green)
143021	BLS-1 NEO (Black-Silver)		
143031	BLS-1 NEO (Sliver-Blue)		
143201	BLS-2 NEO (White-Pink)		
143211	BLS-2 NEO (White-Green)		
143221	BLS-2 NEO (Black-Silver)		



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143231	Binocular Loupe	BLS-2 NEO (Sliver-Blue)
143041		BLS-3 NEO (White-Pink)
143051		BLS-3 NEO (White-Green)
143061		BLS-3 NEO (Black-Silver)
143071		BLS-3 NEO (Sliver-Blue)
143081		BLD-3 NEO (White-Pink)
143091		BLD-3 NEO (White-Green)
143101		BLD-3 NEO (Black-Silver)
143111		BLD-3 NEO (Sliver-Blue)
143121		BLP-4 NEO (White-Pink)
143131		BLP-4 NEO (White-Green)
143141		BLP-4 NEO (Black-Silver)
143151		BLP-4 NEO (Sliver-Blue)
143161		BLP-6 NEO (White-Pink)
143171		BLP-6 NEO (White-Green)
143181		BLP-6 NEO (Black-Silver)
143191		BLP-6 NEO (Sliver-Blue)
110191		Binocular Loupe
110211	BLS-2 TITANIUM	
110221	BLS-3 TITANIUM	
110231	BLD-3 TITANIUM	
110161	BLP-4 TITANIUM	
110171	BLP-6 TITANIUM	
805611	Nose Pad NEO	
197411	Forehead Cushion NEO	
197941	Shield NEO	
197951	Lens Cloth	
197311	Carrying Case NEO	
805991	Nose Pad BETA	
197961	Forehead Cushion BETA	
197921	Shield BETA (3 pieces)	



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197971	Carrying Case BETA	
805971	Nose Pad Eyeglasses	
197421	Cushion Tube (5 pieces)	
197931	Loupe Frame Strap	
197991	Philips Screw Drivers (2 pieces)	

Serial Numbers:

Description	Model Name/Type	Serial Number
Binocular Loupe	BLS-1	04606A001 and later
	BLS-2	04904A005 and later
	BLS-3	05503A003 and later
	BLD-3	05207A001 and later
	BLP-4	05805A004 and later
	BLP-6	06102A005 and later
BETA Frame	Black	06902A022 and later
	Blue	07306A003 and later
	Red	07202A026 and later
NEO Frame	Silver	07602A016 and later
	Black	07402A016 and later
	White-Green White-Pink	07502A019 and later
Binocular Loupe with TITANIUM Frame	BLS-1 TITANIUM	04808B001 and later
	BLS-2 TITANIUM	05108B001 and later
	BLS-3 TITANIUM	05707B005 and later
	BLD-3 TITANIUM	05402A010 and later
	BLP-4 TITANIUM	06002A017 and later
	BLP-6 TITANIUM	06302A009 and later