

	EC Declaration of Conformity- Frames	Revision: 06
		Review Date: 04/12/2019

Manufacturer: Keeler Ltd.
Address: Clewer Hill Rd., Windsor, Berkshire, SL4 4AA
 United Kingdom
Device Name: Frames
Device Classification: Class I
GMDN Classification Code(s) 32036 (headband, reusable)

I, the undersigned, hereby declare that the medical devices specified above and bearing CE marking, conform to the applicable provisions of the Medical Devices Directive (MDD) 93/42/EEC and the transpositions of this amended Directive into national law of the countries of sale.

Keeler hereby certifies that the part numbers listed are in compliance with EU Directive 2011/65/EU (RoHS)

This declaration of conformity is issued under the Sole Responsibility of the manufacturer on the basis of:

- i. Quality Management System Certificate No: LRQ 0943149/E Issued by Lloyds Register Quality Assurance
- ii. Technical File demonstrating conformity with the essential requirements of this Directive and maintained according to MDD Annex VII for devices classified as Class I under MDD Annex IX
- iii. Each device being released to market in accordance with records certifying compliance with applicable product specifications and procedures.

Full Name: Moria Zigman
Position: Senior Regulatory Affairs
 Officer

Signature:



Date: 04/12/2018

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 Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40

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Description	Part number
Headband	
Loupe Headband	2199-P-7259
Frame	
New K Frame – Standard Arm - Black	2199-P-1500
New K Frame – Standard Arm - Blue	2199-P-1519
New K Frame – Standard Arm - Red	2199-P-1527
New K Frame – Long Arm - Black	2199-P-1543
New K Frame – Long Arm - Blue	2199-P-1551
New K Frame – Long Arm - Red	2199-P-1578
Mini Frame	
Small Frame + Case – Black	2199-P-1982
Small Frame + Case – Blue	2199-P-1983
Small Frame + Case – Red	2199-P-1984
Accessories	
Flip Lever	2199-P-7216
Side Shields	2199-P-7240
Western Nose Bridge	2199-P-7531
Asian Nose Bridge	2199-P-7558
Protective Front Shield	2199-P-7574
Comfort Pad	2199-P-7603
Frame Inserts	2199-P-7611