	EC Declaration of Conformity- Visual Acuity Testing	Revision: 05
		Review Date: 04/12/2019

Manufacturer: Keeler Ltd.

Address: Clewer Hill Rd., Windsor, Berkshire, SL4 4AA
United Kingdom

Device Name: Visual Acuity Testing

Device Classification: Class I

GMDN Classification Code(s) 32789


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

Description	Part number
Visual Acuity Testing	
Trial Lens Frame – reduced aperture	2201-P-1121
Plastic Trial Lens Set	2201-P-1228
Reduced Aperture Metal Trial Lens Set	2201-P-1236
Full Aperture Metal Trial Lens Set	2201-P-1244
Sheridan Gardner Orthopic Booklet 6/60 to 6/18	2204-P-1012
Sheridan Gardner Orthopic Booklet 6/18 to 6/6	2204-P-1020
Sheridan Gardner Orthopic Booklet 6/6 to 6/3	2204-P-1039
Sheridan Gardner Complete Set	2204-P-1063
LogMAR 4 metre Test type	2204-P-2365
Stand for 2204-P-2365	2204-P-2445
Peter Rabbit Test Type	2205-P-1004
Sheridan Gardner Orthopic Booklet Near Vision	2205-P-1006
Vocational Reading Test Type	2205-P-1014
Washable Test Type – 4 pages	2205-P-1022
Jager Test Type	2205-P-1057
Thomas the Tank Engine Test type	2205-P-1065
Ishihara Colour Test – 38 plates	2206-P-1008
Ishihara Colour Test – 24 plates	2206-P-1016
Trial Lens Frame	2207-P-1173
Standard Amsler Chart	2215-P-1050
Children’s Trial Lens Set	2207-P-1202
Keeler Acuity Infant Screening Set – 8 cards	2215-P-1085
Keeler Acute Children’s Screening Set – 12 cards	2215-P-1093
Maddox Wing Test	2301-P-1022
Wirt Stereo Fly Test	2406-L-1000