

EC DECLARATION OF CONFORMITY

Manufacturer: Keeler Ltd.

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

Device Name: a. Indirect binocular ophthalmoscope, line powered
b. Indirect binocular ophthalmoscope, battery powered

Device Classification: Class I

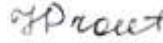
GMDN Classification Code(s) a. 46790 Type P
b. 46792 Type P

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/A Issued by Lloyds Register Quality Assurance, Notified Body (No: 0088) in accordance with the procedure set out in Annex II of this Directive;
- 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:	Irina Proutski	Signature:	
Position:	Senior Regulatory Affairs Officer	Date:	26/6/2014

Keeler Ltd Clewer Hill Road Windsor Berkshire SL4 4AA Tel: +44 (0) 1753 857177 Email: info@keeler.co.uk
Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) **Website:** www.keeler.co.uk

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

All Pupil Indirect 2 (API 2)

Description	Part number
API 2/2 in Carton	1204-P-3036
API 2 Wired Kit with Power/Accessories	1204-P-3038
API 2 Wireless Kit A with Power/Accessories	1204-P-3041
API 2 Wireless with Lithium Battery & Holder	1204-P-3043
API 2 & Wireless Headband	1204-P-3045
API 2/2 Kit 1	1204-P-3100

Monocular Indirect

Description	Part number
Wide Angle Twin Mag Ophthalmoscope	1130-P-1000
Wide Angle	1130-P-5004

Spectra

Description	Part number
Spectra Iris Kit with Black Regular Frame	1205-P-2010
Spectra Iris Kit with Black Large Frame	1205-P-2011
Spectra Iris Kit with Black Small Frame	1205-P-2012
Spectra Iris Kit with Blue Regular Frame	1205-P-2013
Spectra Iris Kit with Blue Large Frame	1205-P-2014
Spectra Iris Kit with Blue Small Frame	1205-P-2015
Spectra Iris Kit with Light Blue Regular Frame	1205-P-2016
Spectra Iris Kit with Light Blue Large Frame	1205-P-2017
Spectra Iris Kit with Light Blue Small Frame	1205-P-2018
Spectra Iris Kit with Red Regular Frame	1205-P-2019
Spectra Iris Kit with Red Large Frame	1205-P-2020

Description	Part number
Spectra Iris Kit with Red Small Frame	1205-P-2021
Spectra Iris Kit with Pink Regular Frame	1205-P-2022
Spectra Iris Kit with Pink Large Frame	1205-P-2023
Spectra Iris Kit with Pink Small Frame	1205-P-2024
Spectra Plus Head Unit	1205-P-5000

Vantage Plus

Description	Part number
Vantage + Bulb, Wired	1204-P-3051
Vantage + Bulb, Standard Battery and Charger	1204-P-3056
Vantage + Bulb, Wired and Accessories	1204-P-3058
Vantage + Bulb, Standard Battery and Accessories	1204-P-3059
Vantage + Bulb, Slimline Battery and Accessories	1204-P-3065
Vantage + Bulb, Slimline Battery and Charger	1204-P-3067
Vantage + LED, Wired	1205-P-1010
Vantage + LED, Wired and Accessories	1205-P-1011
Vantage + LED, Standard Battery and Accessories	1205-P-1015
Vantage + LED, Slimline Battery and Accessories	1205-P-1016
Vantage + LED, Standard Battery and Charger	1205-P-1019
Vantage + LED, Slimline Battery and Charger	1205-P-1020
Vantage + Digital	1205-P-5010

Accessories

Description	Part number
All Pupil Bulbs (Pack of 2)	1012-P-7003
Vantage Plus Bulbs (pack of 2)	1012-P-7006
All Pupil Bulbs (Pack of 2)	1012-P-7003

Description	Part number
Vantage Plus Bulbs (pack of 2)	1012-P-7006
API 2 LED	1012-P-7008
Corneal Lens Attachment for Wide Angle	1130-P-7000
Large Depressor	1201-P-6067
Small Depressor	1201-P-6075
All pupil 2 Teaching Mirror Assembly	1202-P-7117
Vantage + Hi-Mag Assembly	1202-P-7192
Vantage + Teaching Mirror Assembly	1202-P-7205
Spectra Teaching Mirror	1205-P-7000
Wireless Lithium Ion Battery	1919-P-1013
Spectra Plus Rechargeable Battery	1919-P-5215
Corded Lithium Ion Battery	1919-P-5231
Wireless Slimline Lithium Ion Battery	1919-P-5338
Standard Battery Charger Assembly	1941-P-1384
Spectra Double Charger	1941-P-5350
Spectra Plus Lithium Battery Charger & Battery	1941-P-5385
WallPack Power Supply	1945-P-1000
SmartPack Power Supply	1945-P-1001
Slimline Battery Charger Assembly	1945-P-5012
Spectra Frame - Regular - Black	2199-P-1682
Spectra Frame - Regular - Blue	2199-P-1690
Spectra Frame - Regular - Red	2199-P-1703
Spectra Frame - Regular - Light Blue	2199-P-1711
Spectra Frame - Long - Black	2199-P-1738
Spectra Frame - Long - Blue	2199-P-1746
Spectra Frame - Long - Red	2199-P-1754
Spectra Frame - Long - Light Blue	2199-P-1762
Carrying Case	3412-P-7000
Spectra Carrying Case	3412-P-7002