

**EC Declaration of Conformity to:
Medical Device Directive 93/42/EEC**

Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
Manufacturing Site(s):	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
Device Description/Family:	Indirect Ophthalmoscopes (See below Product Schedule)
EC Product Classification:	Class I, Annex IX, Rule 12
GMDN:	<p>46790 – Indirect binocular ophthalmoscope, battery-powered</p> <p>A battery-powered, ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures. It typically consists of a main light to illuminate the interior of the eyeball, a system of lenses and filters and an illuminator beam to eliminate reflexes. Also called a binocular indirect ophthalmoscope (BIO), it produces images that better overcome large refractive errors and subtle colour differences. It can be mounted on a headband or spectacle frames; the batteries may be incorporated, or the power supplied via an electrical cable from an external battery pack.</p> <p>46792 – Indirect binocular ophthalmoscope, line-powered</p> <p>A mains electricity (AC-powered), ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures. It typically consists of a main light to illuminate the interior of the eyeball, a system of lenses and filters and an illuminator beam to eliminate reflexes. Also called a binocular indirect ophthalmoscope (BIO), it produces images that better overcome large refractive errors and subtle colour differences. It can be mounted on a headband or spectacle frames and the power is run through a transformer to reduce this to low-voltage.</p>

We herewith declare, as the sole manufacturer, that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices.

Applied Directives:	<ul style="list-style-type: none"> • Medical Device Directive (MDD) - 93/42/EC • Restriction of Hazardous Substance (RoHS)– 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive – 2012/19/EU • MEDDEV 2.7/1 Rev. 4
Applied Standards:	<ul style="list-style-type: none"> • BS EN ISO 13485:2016 • BS EN ISO 14971:2012 • BS EN ISO 10993-1:2009 • ISO 10993-5:2009 • ISO 10993-10:2010 • IEC 60601-1:2005+ A1:2012 • IEC 60601-1-2:2014 • BS EN 60601-1-6:2010 +A1:2015

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

	<ul style="list-style-type: none">• IEC 62366-1:2008• BS EN ISO 15004-1:2009• BS EN ISO 15004-2:2007• BS EN ISO 15223-1:2016• BS EN 1041:2008 + A1:2013• ISO 14155-1:2003• BS EN 60601-1:2006 +A12:2014
Notified Body:	SGS Belgium NV SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 https://www.sgs.be/en/
CE Certificate Number:	Class I Self Certified
Date of Issuance of Original CE Certificate:	N/A

DofC Reference to Tech File: DofC 01

Rev: 13

Signed: 

Arminster Purewal

Date: 25 Aug 2020

Head of Regulatory Affairs
and Quality Assurance,
Keeler Ltd

Product Schedule: Indirect Ophthalmoscopes

GMDN: 46790		
Part Number	Device Description	Product Classification
1012-P-7008	API 2 LED	I
1204-P-3036	API 2/2 IN CARTON	I
1204-P-3038	API 2/2 KIT A IN CASE	I
1204-P-3041	WIRELESS API 2 KIT A	I
1204-P-3043	WIRELESS API 2 & CHARGER	I
1204-P-3045	WIRELESS ALL PUPIL II	I
1204-P-3100	API 2/2 KIT 1	I
1204-P-4000	WIRELESS API 2 & CHARGER KIT (USA)	I
1205-P-1037	API - WIRELESS KIT	I
1205-P-2000	API LED WIRELESS & SLIMLINE CHARGER	I
1205-P-2001	API LED WIRELESS & CHARGER	I
1205-P-2003	API II LED WIRELESS SLIMLINE WITHOUT CHARGER	I
1205-P-2007	API II LED WIRELESS SLIMLINE STUDENT KIT	I
1205-P-1023	SPECTRA PLUS (INDIAN VERSION)	I
1205-P-1027	SPECTRA IRIS (INDIAN VERSION) & HEADBAND	I
1205-P-5030	SPECTRA IRIS	I
1204-P-1000	WIRELESS VANTAGE & CHARGER KIT (USA)	I
1204-P-3051	VANTAGE PLUS	I
1204-P-3052	WIRELESS VANTAGE PLUS	I
1204-P-3056	WIRELESS VANTAGE PLUS	I
1204-P-3057	WIRELESS VANTAGE PLUS	I
1204-P-3058	VANTAGE PLUS	I
1204-P-3059	WIRELESS VANTAGE PLUS	I
1204-P-3061	VANTAGE+ USA STUDENT KIT-WIRELESS	I
1204-P-3064	VANTAGE PLUS BULB WIRELESS 2 IN CARTON	I
1204-P-3065	VANTAGE PLUS BULB/SLIMLINE KIT A	I
1204-P-3067	VANTAGE PLUS BULB/SLIMLINE & CHARGER	I
1204-P-3068	VANTAGE+ BLB STUDENT KIT - WIRELESS 2	I
1205-P-1013	VANTAGE PLUS LED WIRELESS IN CARTON	I
1205-P-1014	VANTAGE PLUS LED WIRELESS 2	I
1205-P-1015	VANTAGE PLUS LED/STANDARD KIT A	I
1205-P-1016	VANTAGE PLUS LED/SLIMLINE KIT A	I
1205-P-1019	VANTAGE PLUS LED STANDARD & CHARGER	I
1205-P-1020	VANTAGE PLUS LED SLIMLINE CHARGER	I
1205-P-1021	VANTAGE+ LED STUDENT KIT WIRELESS	I
1205-P-1022	VANTAGE PLUS LED/BULB STUDENT KIT WIRELESS	I

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Part Number	Device Description	Product Classification
1205-P-1035	VANTAGE PLUS - WIRELESS KIT	I
1205-P-2009	VANTAGE+ Di INC COMPUTER	I
1205-P-2036	VANTAGE PLUS DIGITAL FIXED FOCUS KIT (US)	I
1205-P-5004	VANTAGE+ LED & WIRELESS HEADBAND	I
1205-P-5005	VANTAGE PLUS LED INCL. WIRELESS HEADBAND	I
1205-P-5010	VANTAGE PLUS DIGITAL KIT	I
1205-P-5010-001	VANTAGE PLUS Di WITHOUT MEMORY STICK	I
1205-P-7003	VANTAGE PLUS DIGITAL KIT UPGRADE	I

GMDN: 46792		
Part Number	Device Description	Product Classification
1204-P-3102	API 2 CORDED WITH BLUE FILTER ASSY	I
1205-P-1036	API - CORDED KIT	I
1205-P-2002	API LED CORDED	I
1205-P-1010	VANTAGE PLUS LED CORDED	I
1205-P-1011	VANTAGE PLUS LED CORDED KIT A	I
1205-P-1034	VANTAGE PLUS - CORDED KIT	I

Accessories		
Part Number	Device Description	
1012-P-5241	VANTAGE+ BULB	
1012-P-5276	VANTAGE+ LED MODULE ASSEMBLY	
1012-P-7006	VANTAGE+ HAL BULB 6V PKT2	
1013-P-7013	API XE BULB 6V PKT2	
1202-P-5816	VANTAGE PLUS (BULB) ON BROWBAR	
1202-P-5859	VANTAGE+ BLB & WIRELESS 2 HEADBAND	
1202-P-6210	API 2 / 2 INDIRECT ASSEMBLY	
1202-P-6237	API 2 WIRELESS INDIRECT ASSEMBLY	
1202-P-7096	HIMAG LENS KIT	
1202-P-7117	TEACHING MIRROR & SCREWDRIVER	
1202-P-7192	VANTAGE PLUS HIMAG	
1202-P-7205	VANTAGE PLUS TEACHING MIRROR ASSEMBLY	
1202-P-7221	VANTAGE PLUS YELLOW FILTER ASSEMBLY	
1202-P-7504	TEACHING MIRROR & YELLOW FILTER	
1205-P-1038	SPECTRA INC BLACK FRAME	
1205-P-1040	SPECTRA PLUS & REGULAR PINK FRAME	
1205-P-2010	SPECTRA IRIS & REGULAR BLACK FRAME	
1205-P-2011	SPECTRA IRIS & LARGE BLACK FRAME	
1205-P-2012	SPECTRA IRIS & SMALL BLACK FRAME	
1205-P-2013	SPECTRA IRIS & REGULAR BLUE FRAME	
1205-P-2014	SPECTRA IRIS & LARGE BLUE FRAME	

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1205-P-2015	SPECTRA IRIS & SMALL BLUE FRAME
1205-P-2019	SPECTRA IRIS & REGULAR RED FRAME
1205-P-2020	SPECTRA IRIS & LARGE RED FRAME
1205-P-2021	SPECTRA IRIS & SMALL RED FRAME
1205-P-2022	SPECTRA IRIS & REGULAR PINK FRAME
1205-P-2023	SPECTRA IRIS & LARGE PINK FRAME
1205-P-2024	SPECTRA IRIS & SMALL PINK FRAME
1205-P-5000	SPECTRA PLUS HEAD UNIT
1205-P-5002	SPECTRA+ FRAME HINGE
1205-P-5003	VANTAGE+ HEAD UNIT - LED
1205-P-5008	VANTAGE DIGITAL ON HEADBAND ONLY
1205-P-5014	API 2 LED BULB ASSY 'COOL WHITE'
1205-P-5015	API 2 LED OPTICAL HEAD UNIT
1205-P-5016	API 2 LED SLIMLINE HEAD UNIT ASSY
1205-P-5018	API 2 LED CORDED HEAD UNIT ASSY
1205-P-5019	API LED SLIMLINE DIMMER PCB ASSY
1205-P-5025	VANTAGE+ DIGITAL KS722 ASSEMBLY
1205-P-7027	VANTAGE+ DIGITAL MIRROR MOUNT ASSEMBLY
1299-P-5168	API 2 WIRELESS HEADBAND ASSY
1299-P-5168S	API WIRELESS HEADBAND SERVICE KIT
1299-P-5192	VANTAGE PLUS WIRELESS HEADBAND
1299-P-5192S	VANTAGE PLUS WIRELESS HEADBAND SERVICE KIT
1299-P-7040	VANTAGE TEACHING MIRROR KIT
1299-P-7075	SPECTRA XE BULB 6V PKT2
1299-P-7091	SLIMLINE WIRELESS HEADBAND ASSY
1919-P-1013	BATTERY PACK ASSEMBLY
1919-P-1015	VANTAGE PLUS LITHIUM BATTERY/CHARGER KIT
1919-P-5231	VANTAGE+ BATTERY BOX ASSEMBLY
1919-P-5282	BATTERY FOR SPECTRA+
1941-P-5334	WIRELESS IND WALL CHARGER ASSY
1941-P-5414	SINGLE LI-ION CHARGER
1945-P-1000	WALL PACK MAINS KIT
1945-P-1001	SMART PACK
1945-P-5012	LITHIUM-ION BATTERY CHARGER
1945-P-5019	SLIMLINE WIRELESS BATTERY CHARGER
3412-P-5047	VANTAGE+ DIGITAL CASE & INSERT