



# Vantage Plus

Indirect ophthalmoscopy enhanced

**Keeler**  
— A world without vision loss —



# Vantage Plus

The Keeler Vantage Plus is designed to save time while providing balanced comfort for extended use in a range of clinical applications through the binocular optical view used in conjunction with a condensing lens.

An Indirect Ophthalmoscope is an AC or battery-powered device containing illumination and viewing optics; and it is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye. The device is intended for use by a trained healthcare professional, and is mounted on the user's head.



## Key features

- Renowned Keeler binocular optics
- Save time during examination with the automated Intelligent Optical System
- Enhance your view by 1.6x with the Hi Mag Lens attachment

# Superior optics without compromise on balance and comfort



## High contrast optics

The compact and high contrast viewing optics use natural LED illumination that gives you brilliantly crisp, glare free, superior views of the retina every time.

## Filters and Apertures

IR/UV filters are built into the optics of the Vantage Plus with optional filters and a choice of 3 apertures plus a soft light diffuser.

P D Range: 48 - 76mm



High contrast Keeler optics



Vantage Plus filters

## Part Numbers

### Vantage Plus Indirect Ophthalmoscope

1205-P-1010	Vantage Plus LED Corded
1205-P-1011	Vantage Plus LED Corded Kit A
1205-P-1014	Vantage Plus LED Wireless In Carton
1205-P-1015	Vantage Plus LED Standard Kit A
1205-P-1016	Vantage Plus LED Slimline Kit A
1205-P-1019	Vantage Plus LED Standard with Charger
1205-P-1020	Vantage Plus LED Slimline with Charger
1205-P-1022	Vantage Plus LED Wireless Student Kit
1205-P-2007	Vantage Plus LED Slimline Student Kit

### Accessories

EP39-53748	Eye Lens Plano (qty 2)
EP39-53799	Rubber Eye Cap (qty 2)
1012-P-5241	Bulb
1201-P-6067	Large Depressor
1201-P-6075	Small Depressor
1202-P-7192	Hi Mag Lens
1205-P-7034	Binocular Indirect Face Shield
1919-P-1013	Standard Battery Pack
1919-P-5338	Slimline Battery for wireless Vantage Plus
1941-P-5335	Standard Charger
1945-P-5019	Slimline Charger for wireless Vantage Plus
2105-K-1159	Volk 20D Black Condensing Lens
2199-P-7136	Lens Cloth
2415-P-7001	Instructions for Use
3412-P-7000	Indirect Carrying Case



# Unique benefits

## Bright white LED illumination for a superior retinal view

The natural LED cooler colour provides brighter, whiter illumination, longer battery life, freedom from purchasing bulbs and a life expectancy of up to 10,000 hours.

Clinically, the superior optics combined with the natural LED illumination could provide greater detail, allowing you to find retinal pathology that was not visible with the Xenon bulb BIO's.



Vantage Plus LED light source



## Intelligent Optical System (IOS) (Patented No. US8132915B)

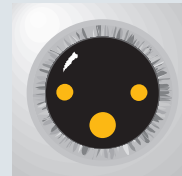
At last - now when you change the aperture, the optics and mirrors automatically adjust for you, without the need to flip another lever!

Keeler has designed this unique one step movement to make your examinations easier and faster.

The (IOS) mechanism (patented) means that when you select the small, medium or large aperture the optics automatically adjust, providing 3 dimensional stereoscopic views of the retina through all pupil sizes.

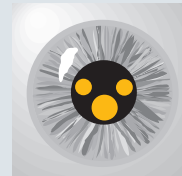
### Large Pupil

When looking through a large fully dilated pupil the optics are separated and the light source remains in the upper position, achieving maximum stereopsis.



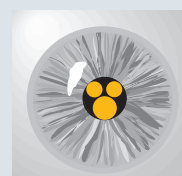
### Intermediate Pupil

The viewing optics and light sources are in a 'mid position' for maximum stereopsis.



### Small Pupil

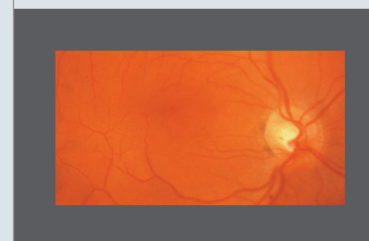
When looking through a small pupil the viewing optics and light source are converged to allow you to view the retina through the smallest pupils stereoscopically.



“Overall it is the best binocular indirect ophthalmoscope I have ever used”

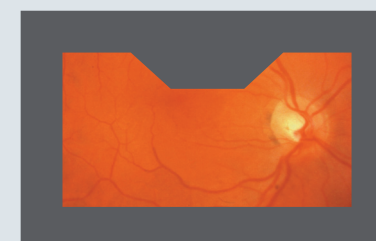
Mr J McAllister FRCS, FRCOph,  
Consultant Ophthalmic Surgeon, Windsor

## Exclusive - IOS Optics allows Small Pupil Imaging without any obstructions



View through Vantage Plus with IOS Optics.

When small pupil is selected there is no obstruction of the retina.



View through NON IOS Optical Systems.

When small pupil is selected there is an obstruction, reducing your clinical information.

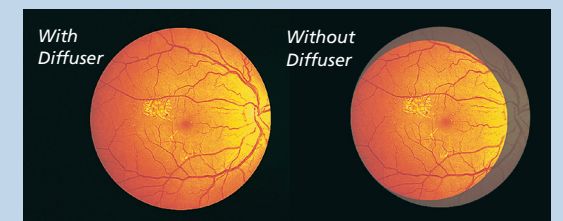


## Teaching Mirror

The Vantage Plus teaching mirror slides on and off with ease allowing two observers to view the retina at the same time.

## Wide angle diffuser

The Keeler wide angle diffuser eliminates shadows on the edge of the condensing lens expanding the field of view significantly, particularly useful during difficult and peripheral examinations. There is also less discomfort for the patient because the light is softer.

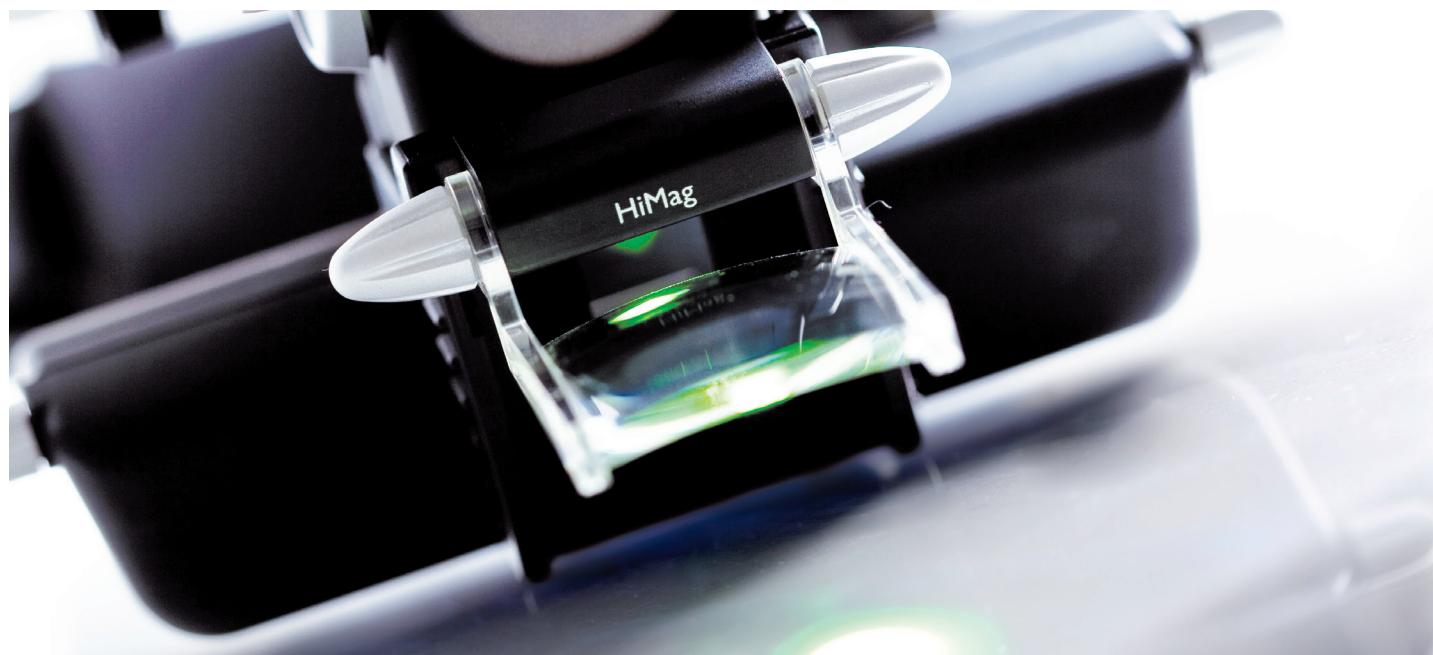


## Slim professional carrying case



Transport your instrument in style and choose if you want to use your wheels or carry it on your shoulder.



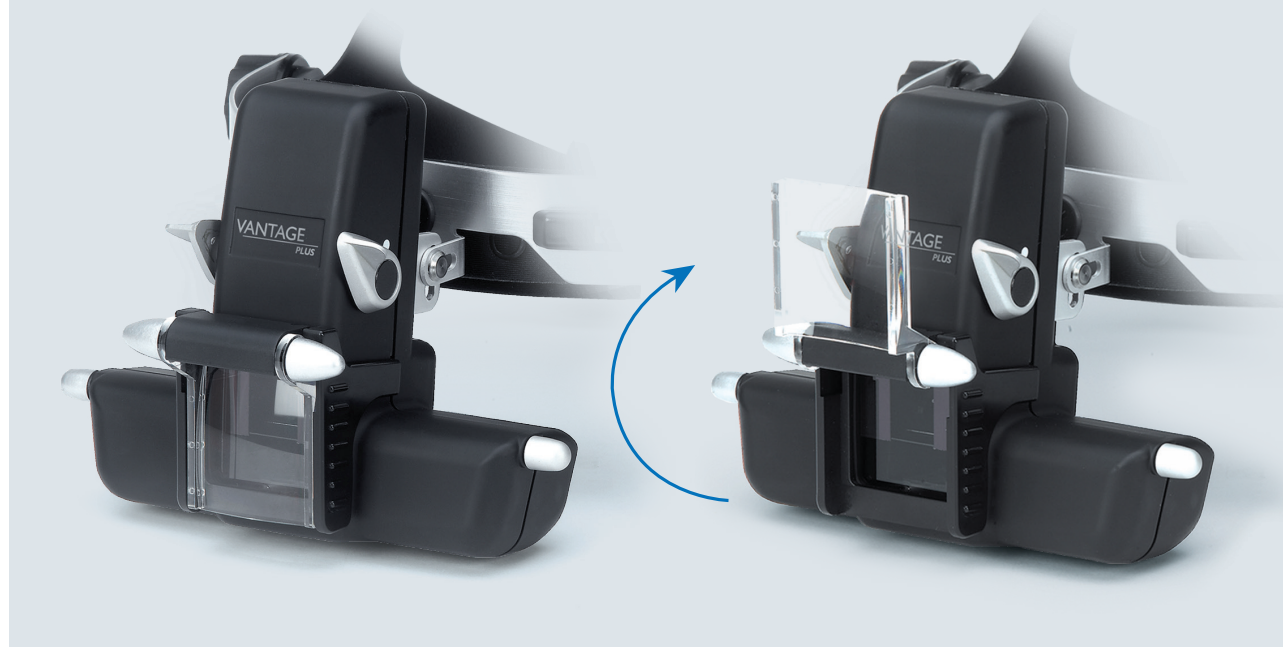


## The HiMag™ lens slides on and off with ease

This unique feature is only offered with the Vantage Plus indirect. It gives you a 1.6X additional magnification than with a condensing lens alone, providing superb stereoscopic images.



Scratch resistant coated optics guarantee high quality images at all times and HiMag™ can be simply flipped out of view when not required.



## Wireless Power Supplies

Keeler wireless technology allows you to move from room to room without any constraints. The chargers are either desktop or wall mountable and store an extra lithium battery as a back up, should you need it.



*Slimline Lithium Polymer Battery  
(paper clip shows scale)*

### Slimline Lithium Polymer Battery

The New Slimline Lithium Polymer battery can give you up to 6 hours of use, weighs only 53 grams, and is nearly 70% lighter than the standard battery. It is also much smaller and can fit nicely into the palm of your hand.

### Slimline Wireless Charger

The new wall mountable charger remains as durable as the Standard Wireless battery charger with the facility to store your extra battery in the top compartment. The charger has an easy release button to remove your extra battery.



*Slimline Wireless Charger*

*Slimline Lithium  
Polymer Battery*



*Slimline Lithium Polymer Battery*

### Standard Lithium Battery

Our original lithium battery lasts up to 11 hours of use and fits neatly into the charging unit.



### Standard Wireless Charger

The Standard Wireless Charger can be wall or desk mounted with space for a spare battery, which means you will always have a back up. An LED indicates when the battery needs charging.



*Standard  
Lithium Battery*



# Wired Power Supplies

## SmartPack

SmartPack is a stylish power supply system that combines 3 options in one product.

No longer will you need to purchase a portable system for domiciliary use, another system for mounting on your wall and another for tabletop use.

## WallPack

Alternatively, if your power supply needs to be stationary you can purchase the WallPack which fits neatly on the wall. Your indirect can be mounted on the bracket it comes with.



WallPack



SmartPack

Which system is right for you?

Vantage Plus Usable Life	
Power Source	Natural LED
Slimline Battery	6 hours*
Standard Battery	11 hours*
SmartPack	17 hours*

\* This measurement is based upon the illumination being used at normal examination power

“I used the Plus almost daily for four months before I had to recharge the battery”

Todd J. Purkiss, M.D., Ph.D., Chief Resident, Ophthalmology & Visual Sciences, University of Louisville

# The Keeler Binocular Indirect Face Shield

Helping doctors stay safe

Providing a barrier between both patients and user to reduce potential transmission of harmful virus, designed with a simple pop on and off attachment mechanism.





# What's in the box?

## Vantage Plus Indirect Ophthalmoscope

- 1205-P-1010  
VANTAGE PLUS LED  
CORDED

  - Vantage Plus Indirect Ophthalmoscope
  - Corded assembly
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1011  
VANTAGE PLUS LED  
CORDED WITH  
ACCESSORIES KIT

  - Vantage Plus Indirect Ophthalmoscope
  - Smartpack power supply
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Carry case
  - Teaching mirror
  - Blue Volk 20D condensing lens
  - Small thimble
  - Large thimble
  - FBO charts pad of 50
  - Set of 12 coloured pencils
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1014  
VANTAGE PLUS LED  
WIRELESS IN CARTON

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Slimline battery pack x2
  - Charger
  - Transformer
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1015  
VANTAGE PLUS LED  
STANDARD WITH  
ACCESSORIES KIT

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Standard battery pack
  - Charger
  - Carry case
  - Teaching mirror
  - Blue Volk 20D condensing lens
  - Small thimble
  - Large thimble
  - FBO charts pad of 50
  - Set of 12 coloured pencils
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1016  
VANTAGE PLUS LED  
SLIMLINE WITH  
ACCESSORIES KIT

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Slimline battery pack
  - Charger
  - Carry case
  - Teaching mirror
  - Blue Volk 20D condensing lens
  - Small thimble
  - Large thimble
  - FBO charts pad of 50
  - Set of 12 coloured pencils
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1019  
VANTAGE PLUS LED  
STANDARD WITH  
WALL-MOUNTED  
CHARGER

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Standard battery pack
  - Wall-mounted charging unit
  - Transformer
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

- 1205-P-1020  
VANTAGE PLUS LED  
SLIMLINE WITH  
WALL-MOUNTED  
CHARGER

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Slimline battery pack
  - Wall-mounted charging unit
  - Transformer
  - Lens cloth
  - +2D and plano ocular lenses
  - Instructions for use

## Vantage Plus Student Sets

- 1205-P-1022  
VANTAGE PLUS LED  
STANDARD WIRELESS  
STUDENT KIT







  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Standard battery pack
  - Charger
  - Carry case
  - Teaching mirror
  - Transformer
  - Lens cloth
  - +2D and plano ocular lenses
  - Halogen bulb insert
  - Instructions for use

- 1205-P-2007  
VANTAGE PLUS LED  
SLIMLINE WIRELESS  
STUDENT KIT

  - Vantage Plus Indirect Ophthalmoscope
  - Keeler BIO face shield
  - Hi-mag lens attachment
  - Slimline battery pack
  - Charger
  - Carry case
  - Teaching mirror
  - Transformer
  - Lens cloth
  - +2D and plano ocular lenses
  - Halogen bulb insert
  - Instructions for use

# Specifications

## Vantage Plus System

OCULAR EYE LENSES	+2D as standard (plano optional)
LIGHT OUTPUT	1000 Lux
COLOUR TEMPERATURE OF LED	3800K
ILLUMINATION MIRROR ADJUSTMENT ABOUT CENTRE AXIS	84mm up, 53 mm down
ADJUSTMENT RANGE OF OPTICS	+/- 4 degrees
WORKING DISTANCE	Nominal 440mm
PUPIL SIZE	1-10mm
PD RANGE	48-76mm
BATTERY	Up to 2 hours continuous on a single charge
CLEANING	Wipe with water / isopropyl alcohol solution (70% IPA by volume)
FILTERS	 Cobalt Blue  Red-free  Diffuser
PATCH DIAMETER	20mm, 40mm, 60mm
APERTURE	 Large  Intermediate  Small
TEMPERATURE LIMITS	Operation +10°C to +35°C Storage -10°C to +55°C Transport -40°C to +70°C
HUMIDITY LIMITS	Operation 30% to 75% Storage 10% to 95% Transport 10% to 95%

## Electrical Ratings

INPUT MAINS DATA	100-240V - 50/60Hz
POWER SUPPLY RATING	12V : 2.5amps
PHOTOCHEMICAL SOURCE RADIANCE	1mm aperture (mW cm <sup>-2</sup> sr <sup>-1</sup> )
APHAKIC, LA (305-700nm)	1.32
PHAKIC, LB (380-700nm)	1.16

## Dimensions and Weight

DIMENSIONS	150 x 230 x 310mm (HxWxD)
WEIGHT	596g

## Classification and Safety Standards

CLASSIFICATION	Class II Equipment. Type B protection against shock
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## Vantage Plus Overview

The Keeler Vantage plus is a head-mounted indirect ophthalmoscope, designed to save time while providing balanced comfort for extended use in a range of clinical applications through the illuminated binocular optical view.

This is intended to be used in conjunction with a condensing lens as prescribed through indirect ophthalmoscopy techniques to illuminate and examine the fundus.

This equipment is to be used only by a healthcare professional.

### More Keeler Instruments

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### Got a question? - Call us

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China: +86-18512119109

**Keeler**  
— A world without vision loss —



A **Halma** company

### Manufacturing address



Keeler Ltd. Clewer Hill Road Berkshire SL4 4AA UK





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

<b>Legal Manufacturer:</b>	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
<b>Manufacturing Site(s):</b>	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
<b>EU Authorised Representative</b>	Visiometrics, S.L., Vinyals, 131 08221 Terrassa, Spain
<b>Device Description/Family:</b>	Indirect Ophthalmoscopes (See below Product Schedule)
<b>EC Product Classification:</b>	Class I, Annex IX, Rule 12
<b>GMDN:</b>	<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.

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

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Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) Website: [www.keeler.co.uk](http://www.keeler.co.uk)  
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"> <li>• IEC 60601-1:2005+ A1:2012</li> <li>• IEC 60601-1-2:2014</li> <li>• BS EN 60601-1-6:2010 +A1:2015</li> <li>• IEC 62366-1:2008</li> <li>• BS EN ISO 15004-1:2009</li> <li>• BS EN ISO 15004-2:2007</li> <li>• BS EN ISO 15223-1:2016</li> <li>• BS EN 1041:2008 + A1:2013</li> <li>• ISO 14155-1:2003</li> <li>• BS EN 60601-1:2006 +A12:2014</li> </ul>
<b>Notified Body:</b>	<b>SGS Belgium NV</b> SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 <a href="https://www.sgs.be/en/">https://www.sgs.be/en/</a>
<b>CE Certificate Number:</b>	Class I Self Certified
<b>Date of Issuance of Original CE Certificate:</b>	N/A

**DofC Reference to Tech File: DofC 01**

**Rev: 15**

**Signed:** 

**Arminder Purewal**

**Date:** 19 Jan 2021

**Head of Regulatory Affairs &  
Quality Assurance, Keeler Ltd**



## Product Schedule: Indirect Ophthalmoscopes

<b>GMDN: 46790</b>		
<b>Part Number</b>	<b>Device Description</b>	<b>Product Classification</b>
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-3039	VANTAGE/2 KIT IN CASE	I
1204-P-3041	WIRELESS API 2 KIT A	I
1204-P-3045	WIRELESS ALL PUPIL II	I
1204-P-3061	VANTAGE+ USA STUDENT KIT-WIRELESS	I
1204-P-3064	VANTAGE PLUS BULB WIRELESS 2 IN CARTON	I
1204-P-3066	VANTAGE+ BLB & WIRELESS 2 CHARGER	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-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-1017	VANTAGE+ LED & WIRELESS CHARGER	I
1205-P-1018	VANTAGE+ LED & WIRELESS 2 CHARGER	I
1205-P-1019	VANTAGE PLUS LED STANDARD & CHARGER	I

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Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) Website: [www.keeler.co.uk](http://www.keeler.co.uk)  
Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40

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
1205-P-2035	VANTAGE PLUS DIGITAL/ANALOGUE FIXED FOCUS KIT	I
1205-P-2036	VANTAGE PLUS DIGITAL FIXED FOCUS KIT (US)	I
1205-P-1035	VANTAGE PLUS - WIRELESS KIT	I
1205-P-2009	VANTAGE+ Di INC COMPUTER	I
1205-P-5004	VANTAGE+ LED & WIRELESS HEADBAND	I
1205-P-5005	VANTAGE PLUS LED INCL. WIRELESS HEADBAND	I
1205-P-5009	VANTAGE+ DIGITAL INDIRECT	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

<b>GMDN: 46792</b>		
<b>Part Number</b>	<b>Device Description</b>	<b>Product Classification</b>
1204-P-3060	VANTAGE+ USA STUDENT KIT CORDED	I
1204-P-3062	VANTAGE+ BASIC KIT (1.5M CABLE)	I
1204-P-3063	VANTAGE+ USA STUDENT KIT (1.5m)	I
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-1012	VANTAGE+ LED USA STUDENT KIT CORD	I
1205-P-1034	VANTAGE PLUS - CORDED KIT	I



<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1012-P-5241	VANTAGE+ BULB
1012-P-5276	VANTAGE+ LED MODULE ASSEMBLY
1012-P-7003	API HAL BULB 6V PKT2
1012-P-7006	VANTAGE+ HAL BULB 6V PKT2
1012-P-7009	API 2 (LED)
1013-P-7013	API XE BULB 6V PKT2
1201-P-7000	CHARTS-FBO-PAD OF 50
1202-P-5787	VANTAGE+ PROJECTION DOUBLET
1202-P-5816	VANTAGE PLUS (BULB) ON BROWBAR
1202-P-5824	VANTAGE+ CABLE ASSEMBLY
1202-P-5859	VANTAGE+ BLB & WIRELESS 2 HEADBAND
1202-P-6202	API 2/2 CABLE ASSY
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
1203-P-2100	VANTAGE
1205-P-1000	SPECTRA PLUS & BLUEZ REGULAR FRAME
1205-P-1001	SPECTRA PLUS & RED REGULAR FRAME
1205-P-1002	SPECTRA PLUS & BLACK REGULAR FRAME
1205-P-1003	SPECTRA PLUS & LIGHT BLUE REGULAR FRAME
1205-P-1004	SPECTRA PLUS & BLUE LT FRAME
1205-P-1005	SPECTRA PLUS & RED LT FRAME
1205-P-1006	SPECTRA PLUS & BLACK LT FRAME
1205-P-1007	SPECTRA PLUS & LIGHT BLUE LT FRAME
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
1205-P-2015	SPECTRA IRIS & SMALL BLUE FRAME
1205-P-2016	SPECTRA IRIS & REGULAR LIGHT BLUE FRAME
1205-P-2017	SPECTRA IRIS & LARGE LIGHT BLUE FRAME
1205-P-2018	SPECTRA IRIS & SMALL LIGHT 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

**Keeler Ltd** Clewer Hill Road Windsor Berkshire SL4 4AA Tel: +44 (0) 1753 857177 Email: [info@keeler.co.uk](mailto:info@keeler.co.uk)  
 Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) **Website:** [www.keeler.co.uk](http://www.keeler.co.uk)  
 Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40



<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1201-P-6067	LARGE THIMBLE COMPLETE FBO
1201-P-6075	SMALL THIMBLE COMPLETE FBO
1202-P-5787	VANTAGE+ PROJECTION DOUBLET
1202-P-5824	VANTAGE+ CABLE ASSY
1202-P-5832	VANTAGE+ WIRELESS CABLE ASSY
1202-P-6202	API 2/2 CABLE ASSY
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-5011	VANTAGE+ DIGITAL MINI USB ASSY
1205-P-5012	API LED PCB
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-5020	V+ DIGITAL ADJUSTABLE LENS ASSY
1205-P-5024	VANTAGE+ DIGITAL DIMMER PCB ASSY
1205-P-5025	VANTAGE+ DIGITAL KS722 ASSEMBLY
1205-P-7001	VANTAGE+ DIGITAL FOOTSWITCH
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
1807-P-1607	KEELER PALM BPM BLUE+ADULT CUFF
1919-P-1003	POWER PACK (UK)
1919-P-1012	POWER PACK (WORLD KIT)
1919-P-1013	BATTERY PACK ASSEMBLY
1919-P-1015	VANTAGE PLUS LITHIUM BATTERY/CHARGER KIT
1919-P-5215	SPECTRA BATTERY PACK ASSY
1919-P-5223	SPECTRA+ BATTERY BOX POT PCB
1919-P-5231	VANTAGE+ BATTERY BOX ASSEMBLY
1919-P-5282	BATTERY FOR SPECTRA+
1919-P-5303	SPECTRA+ BATTERY BOX PCB ASSY
1941-P-5334	WIRELESS IND WALL CHARGER ASSY
1919-P-5338	SLIMLINE LITHIUM ION BATTERY
1941-P-5414	SINGLE LI-ION CHARGER
1945-P-1000	WALL PACK MAINS KIT
1945-P-1001	SMART PACK

**Keeler Ltd** Clewer Hill Road Windsor Berkshire SL4 4AA Tel: +44 (0) 1753 857177 Email: [info@keeler.co.uk](mailto:info@keeler.co.uk)  
Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) Website: [www.keeler.co.uk](http://www.keeler.co.uk)  
Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40



<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1945-P-5012	LITHIUM-ION BATTERY CHARGER
1945-P-5013	WIRELESS 2 CHARGER MAIN PCB
1945-P-5014	WIRELESS 2 CHARGER LED PCB ASSY
1945-P-5015	CHARGER TOP ASSEMBLY
1945-P-5019	SLIMLINE WIRELESS BATTERY CHARGER
1945-P-7000	REFRACTION STAND POWER ADAPTOR
1952-P-1347	FISON TRANSFORMER KIT 120V (HOSPITAL PLUG)
2004-P-1021	LED HEADLAMP CO-AXIAL
2099-P-5010	MK2 HEADBAND ASSY
2199-P-5886	KEELER REGULAR FRAME – BLUE Z
2199-P-5894	KEELER REGULAR FRAME - RED
2199-P-6326	SPECTRA IRIS FRAME INSERT ASSY
3412-P-5047	VANTAGE+ DIGITAL CASE & INSERT
3412-P-7000	VANTAGE+ SOFT CASE & INSERT
3412-P-7002	SPECTRA+ SOFT CASE
EP39-22079	SMART PACK BATTERY

Keeler Ltd  
Clewer Hill Road  
Windsor  
Berkshire  
SL4 4AA  
UNITED KINGDOM

21 Apr 2023

**Subject: Justification for Extension of CE Certifications issued under the Medical Device Directive 93/42/EEC (MDD).**

As you may be aware, The European Parliament has voted to adopt an extension of the transition period for the EU Medical Device Regulations and to extend the validity of the current MDD EC Certifications.

MDR deadlines have now been extended based upon the risk class of the Medical Device(s) as indicated in the Extension Letter supplied by our Notified Body SGS (See supporting Extension Letter).

We, Keeler Ltd (the Legal Manufacturer) hereby declare that as per Medical Device Directive 93/42/EEC, our EC Certifications are deemed valid and permits us to continue placing our Medical Devices on the market which remain compliant under the Medical Devices Directive (MDD) in accordance with the Extension Letter.

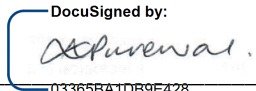
CE certifications we currently hold are as follows:

EC Certification	EC Certification Number	Expiry Date	Extended Expiry
SGS EC Annex II Certificate (excl. Section 4)	GB20 965236	23 Mar 2023	31 Dec 2028
SGS EC Annex V Certificate	GB20/965237	23 Mar 2023	31 Dec 2028

As the Legal Manufacturer I can also confirm the following:

- 1) There have been no significant changes in the design and purpose of the medical device(s);
- 2) The medical device(s) do not pose an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of health care.

Yours faithfully,

Signed:  Date: 21/04/2023  
03365BA1DB9E428...

Arminder Purewal  
Head of Global Regulatory Affairs & EMEA Quality Assurance  
Keeler Ltd



Keeler Ltd  
Clewer Hill Road  
Windsor, Berkshire  
SL4 4AA, UK

27/03/2023

**Confirmation Letter Reference: CLNB1639 CL-0005**

To whom it may concern,

**Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Keeler Ltd  
Clewer Hill Road  
Windsor, Berkshire  
SL4 4AA, UK  
SRN Number: GB-MF-000009031

Visiometrics, S.L  
Vinyals, 131  
08221, Terrassa  
Spain

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



Virginie SILORET  
Global Medical Device Certification Manager  
Email: [Virginie.siloret@sgs.com](mailto:Virginie.siloret@sgs.com)  
Phone : +41 22 739 98 58

#### Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Applanation Tonometer to aid diagnosis and measurement of intraocular pressure / 50552727ATONOMETER8Y	Class I devices placed on the market in measuring condition	N/A	GB20/965237; NB1639
Disposable Applanation Tonometer Cone for use in	Class I devices placed on the market in	N/A	GB20/965237; NB1639



Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
testing of intraocular pressure /50552727TONOCLEARR7	sterile condition		
Disposable Cryo Probe for use with Ophthalmic Surgery Devices / 50552727CRYOPROBESJ9	Class IIa	N/A	GB20/965237; NB1639
Keeler Cryomatic MKII Console & Pencils for use in ophthalmic Surgery / 50552727CRYOCONSOLEBT (Cryo Console MKII) and 50552727CRYOPROBESJ9 (Probes)	Class IIb	N/A	GB20/965236; NB1639
Laser Indirect Ophthalmoscope (LIO) for use in ophthalmic surgical procedures / 50552727LINDOSCOPE67	Class IIb	N/A	GB20/965236; NB1639
Pulsair Intellipuff - Non- Contact Tonometer / 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Pulsair Desktop Tonometer/ 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Tonocare – Non- Contact Tonometer / 50552727TONOCARE8H	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT) / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT), Z-Type / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639

## Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
27.03.2023	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607



Keeler Ltd  
Clewer Hill Road  
Windsor, Berkshire  
SL4 4AA, UK

27/03/2023

**Confirmation Letter Reference: CLNB1639 CL-0005**

To whom it may concern,

**Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

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Windsor, Berkshire  
SL4 4AA, UK  
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Visiometrics, S.L  
Vinyals, 131  
08221, Terrassa  
Spain

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- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
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On behalf of the Notified Body SGS Belgium NV 1639,



Virginie SILORET  
Global Medical Device Certification Manager  
Email: [Virginie.siloret@sgs.com](mailto:Virginie.siloret@sgs.com)  
Phone : +41 22 739 98 58

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Applanation Tonometer to aid diagnosis and measurement of intraocular pressure / 50552727ATONOMETER8Y	Class I devices placed on the market in measuring condition	N/A	GB20/965237; NB1639
Disposable Applanation Tonometer Cone for use in	Class I devices placed on the market in	N/A	GB20/965237; NB1639



Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Disposable Cryo Probe for use with Ophthalmic Surgery Devices / 50552727CRYOPROBESJ9	Class IIa	N/A	GB20/965237; NB1639
Keeler Cryomatic MKII Console & Pencils for use in ophthalmic Surgery / 50552727CRYOCONSOLEBT (Cryo Console MKII) and 50552727CRYOPROBESJ9 (Probes)	Class IIb	N/A	GB20/965236; NB1639
Laser Indirect Ophthalmoscope (LIO) for use in ophthalmic surgical procedures / 50552727LINDOSCOPE67	Class IIb	N/A	GB20/965236; NB1639
Pulsair Intellipuff - Non- Contact Tonometer / 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Pulsair Desktop Tonometer/ 50552727PAIRDESKTOPU3	Class IIa	N/A	GB20/965236; NB1639
Tonocare – Non- Contact Tonometer / 50552727TONOCARE8H	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT) / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639
Keeler Digital Applanation Tonometer (D-KAT), Z-Type / 50552727DKATLA	Class IIa	N/A	GB20/965236; NB1639

## Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
27.03.2023	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607

## Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**Keeler Cryomatic MKII Console & Pencils for use in ophthalmic surgery  
Laser Indirect Ophthalmoscope (LIO)  
for use in ophthalmic surgical procedures**

**Tonometers to aid diagnosis and measurement of intraocular pressures:  
Pulsair Intellipuff – Non-Contact Tonometer  
TonoCare – Non-Contact Tonometer  
Pulsair Desk Top Tonometer  
Keeler Digital Applanation Tonometer (D-KAT)  
Keeler Digital Applanation Tonometer (D-KAT), Z Type**


Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 May 2021 until 23 March 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 10 September 1995

Certification is based on reports numbered GB/PC 240569

Authorised by



Global Medical Devices Head of Notified Body

## SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 [www.sgs.com](http://www.sgs.com)

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

Page 1 of 1





The management system of

**Keeler Ltd**

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**

on medical devices, Annex V

For the following products

**Applanation Tonometer to aid diagnosis  
and measurement of intraocular pressure**

**Disposable Applanation Tonometer Cone  
for use in testing of intraocular pressure**

**Disposable Cryo Probe for use with Ophthalmic Surgery Devices**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 May 2021 until 23 March 2023  
and remains valid subject to satisfactory surveillance audits.  
Issue 2. Certified since 08 September 2009

Certification is based on reports numbered GB/PC/ 240569

Authorised by



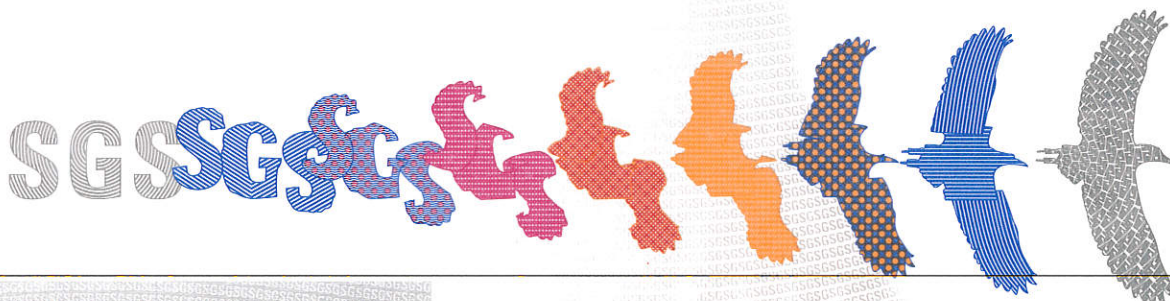
Global Medical Devices Head of Notified Body

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 [www.sgs.com](http://www.sgs.com)

LPMD5008 - Certificate CE1639 AnnexV\_EN Rev. 02

Page 1 of 1



Certificate GB19/964765

SGS

The management system of

**Keeler Ltd**

Clewer Hill Road Windsor Berkshire SL4 4AA United Kingdom

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Design, Development and manufacture, distribution & service of Optometric and Ophthalmic medical devices and equipment.

This certificate is valid from 23 March 2023 until 23 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 09 October 1995

*Jonathan M. Hall*

Authorised by  
Jonathan Hall  
Global Head - Certification Services

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)



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*Anexa nr. 1*  
*La Procedurile administrative pentru notificarea*  
*dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**  
pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. 1 din 11.07.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- 1) Oftalmoscop indirect, Ref.: 1205-P-1020

Se anexează următoarele acte:

- 1) Declarație de Conformitate, din 19.01.2021;
- 2) Certificat ISO 13485, No. GB19/964765 din 23.03.2023 ;
- 3) Scirsoare de autorizare din 16.10.2022.

Data 11.07.2023

Semnătura \_\_\_\_\_

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	



*Anexa nr. 2*  
*La Procedurile administrative pentru notificarea*  
*dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu  
17/6

declar pe proprie răspundere, cunoscând prevederile art. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- 1) Declarație de Conformitate, din 19.01.2021;
- 2) Certificat ISO 13485, No. GB19/964765 din 23.03.2023 ;
- 3) Scirsoare de autorizare din 16.10.2022.

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția*

*Semnătura* \_\_\_\_\_

*Grabazei Alexandru, director general.*

*Data 11.07.2023*

Date: October 16<sup>th</sup>, 2022  
Windsor, UK

**Authorization Letter**

To Whom It May Concern

Herewith we, Keeler Ltd, who are established and reputable manufacturer of Ophthalmic Products and accessories having factories at Windsor, UK, SL4 4AA, Clewer Hill Road, authorize the company

**FCPC "DataControl" SRL**  
**20 Melestiu Street, MD-2001,**  
**Chisinau, Republic of Moldova**

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of medical devices manufactured by us. Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose the above company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, to conduct any field actions which may be necessary in accordance with legislation of Republic of Moldova.

Registration certificates must be issued on the name of Keeler Ltd.

This authorization letter is valid for a period of 12 (twelve) months from the date of issue.

Signed for and on behalf of Keeler Ltd



Abbas Sotoudeh  
Managing Director

KEELER LIMITED  
CLEWER HILL ROAD  
WINDSOR  
BERKSHIRE SL4 4AA

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

<b>Legal Manufacturer:</b>	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
<b>Manufacturing Site(s):</b>	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
<b>EU Authorised Representative</b>	Visiometrics, S.L., Vinyals, 131 08221 Terrassa, Spain
<b>Device Description/Family:</b>	Indirect Ophthalmoscopes (See below Product Schedule)
<b>EC Product Classification:</b>	Class I, Annex IX, Rule 12
<b>GMDN:</b>	<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.

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

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	<ul style="list-style-type: none"> <li>• IEC 60601-1:2005+ A1:2012</li> <li>• IEC 60601-1-2:2014</li> <li>• BS EN 60601-1-6:2010 +A1:2015</li> <li>• IEC 62366-1:2008</li> <li>• BS EN ISO 15004-1:2009</li> <li>• BS EN ISO 15004-2:2007</li> <li>• BS EN ISO 15223-1:2016</li> <li>• BS EN 1041:2008 + A1:2013</li> <li>• ISO 14155-1:2003</li> <li>• BS EN 60601-1:2006 +A12:2014</li> </ul>
<b>Notified Body:</b>	<b>SGS Belgium NV</b> SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 <a href="https://www.sgs.be/en/">https://www.sgs.be/en/</a>
<b>CE Certificate Number:</b>	Class I Self Certified
<b>Date of Issuance of Original CE Certificate:</b>	N/A

**DofC Reference to Tech File: DofC 01**

**Rev: 15**

**Signed:** 

**Arminder Purewal**

**Date:** 19 Jan 2021

**Head of Regulatory Affairs &  
Quality Assurance, Keeler Ltd**

## Product Schedule: Indirect Ophthalmoscopes

<b>GMDN: 46790</b>		
<b>Part Number</b>	<b>Device Description</b>	<b>Product Classification</b>
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-3039	VANTAGE/2 KIT IN CASE	I
1204-P-3041	WIRELESS API 2 KIT A	I
1204-P-3045	WIRELESS ALL PUPIL II	I
1204-P-3061	VANTAGE+ USA STUDENT KIT-WIRELESS	I
1204-P-3064	VANTAGE PLUS BULB WIRELESS 2 IN CARTON	I
1204-P-3066	VANTAGE+ BLB & WIRELESS 2 CHARGER	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-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-1017	VANTAGE+ LED & WIRELESS CHARGER	I
1205-P-1018	VANTAGE+ LED & WIRELESS 2 CHARGER	I
1205-P-1019	VANTAGE PLUS LED STANDARD & CHARGER	I

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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
1205-P-2035	VANTAGE PLUS DIGITAL/ANALOGUE FIXED FOCUS KIT	I
1205-P-2036	VANTAGE PLUS DIGITAL FIXED FOCUS KIT (US)	I
1205-P-1035	VANTAGE PLUS - WIRELESS KIT	I
1205-P-2009	VANTAGE+ Di INC COMPUTER	I
1205-P-5004	VANTAGE+ LED & WIRELESS HEADBAND	I
1205-P-5005	VANTAGE PLUS LED INCL. WIRELESS HEADBAND	I
1205-P-5009	VANTAGE+ DIGITAL INDIRECT	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

<b>GMDN: 46792</b>		
<b>Part Number</b>	<b>Device Description</b>	<b>Product Classification</b>
1204-P-3060	VANTAGE+ USA STUDENT KIT CORDED	I
1204-P-3062	VANTAGE+ BASIC KIT (1.5M CABLE)	I
1204-P-3063	VANTAGE+ USA STUDENT KIT (1.5m)	I
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-1012	VANTAGE+ LED USA STUDENT KIT CORD	I
1205-P-1034	VANTAGE PLUS - CORDED KIT	I



<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1012-P-5241	VANTAGE+ BULB
1012-P-5276	VANTAGE+ LED MODULE ASSEMBLY
1012-P-7003	API HAL BULB 6V PKT2
1012-P-7006	VANTAGE+ HAL BULB 6V PKT2
1012-P-7009	API 2 (LED)
1013-P-7013	API XE BULB 6V PKT2
1201-P-7000	CHARTS-FBO-PAD OF 50
1202-P-5787	VANTAGE+ PROJECTION DOUBLET
1202-P-5816	VANTAGE PLUS (BULB) ON BROWBAR
1202-P-5824	VANTAGE+ CABLE ASSEMBLY
1202-P-5859	VANTAGE+ BLB & WIRELESS 2 HEADBAND
1202-P-6202	API 2/2 CABLE ASSY
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
1203-P-2100	VANTAGE
1205-P-1000	SPECTRA PLUS & BLUEZ REGULAR FRAME
1205-P-1001	SPECTRA PLUS & RED REGULAR FRAME
1205-P-1002	SPECTRA PLUS & BLACK REGULAR FRAME
1205-P-1003	SPECTRA PLUS & LIGHT BLUE REGULAR FRAME
1205-P-1004	SPECTRA PLUS & BLUE LT FRAME
1205-P-1005	SPECTRA PLUS & RED LT FRAME
1205-P-1006	SPECTRA PLUS & BLACK LT FRAME
1205-P-1007	SPECTRA PLUS & LIGHT BLUE LT FRAME
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
1205-P-2015	SPECTRA IRIS & SMALL BLUE FRAME
1205-P-2016	SPECTRA IRIS & REGULAR LIGHT BLUE FRAME
1205-P-2017	SPECTRA IRIS & LARGE LIGHT BLUE FRAME
1205-P-2018	SPECTRA IRIS & SMALL LIGHT 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

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<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1201-P-6067	LARGE THIMBLE COMPLETE FBO
1201-P-6075	SMALL THIMBLE COMPLETE FBO
1202-P-5787	VANTAGE+ PROJECTION DOUBLET
1202-P-5824	VANTAGE+ CABLE ASSY
1202-P-5832	VANTAGE+ WIRELESS CABLE ASSY
1202-P-6202	API 2/2 CABLE ASSY
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-5011	VANTAGE+ DIGITAL MINI USB ASSY
1205-P-5012	API LED PCB
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-5020	V+ DIGITAL ADJUSTABLE LENS ASSY
1205-P-5024	VANTAGE+ DIGITAL DIMMER PCB ASSY
1205-P-5025	VANTAGE+ DIGITAL KS722 ASSEMBLY
1205-P-7001	VANTAGE+ DIGITAL FOOTSWITCH
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
1807-P-1607	KEELER PALM BPM BLUE+ADULT CUFF
1919-P-1003	POWER PACK (UK)
1919-P-1012	POWER PACK (WORLD KIT)
1919-P-1013	BATTERY PACK ASSEMBLY
1919-P-1015	VANTAGE PLUS LITHIUM BATTERY/CHARGER KIT
1919-P-5215	SPECTRA BATTERY PACK ASSY
1919-P-5223	SPECTRA+ BATTERY BOX POT PCB
1919-P-5231	VANTAGE+ BATTERY BOX ASSEMBLY
1919-P-5282	BATTERY FOR SPECTRA+
1919-P-5303	SPECTRA+ BATTERY BOX PCB ASSY
1941-P-5334	WIRELESS IND WALL CHARGER ASSY
1919-P-5338	SLIMLINE LITHIUM ION BATTERY
1941-P-5414	SINGLE LI-ION CHARGER
1945-P-1000	WALL PACK MAINS KIT
1945-P-1001	SMART PACK

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<b>Accessories</b>	
<b>Part Number</b>	<b>Device Description</b>
1945-P-5012	LITHIUM-ION BATTERY CHARGER
1945-P-5013	WIRELESS 2 CHARGER MAIN PCB
1945-P-5014	WIRELESS 2 CHARGER LED PCB ASSY
1945-P-5015	CHARGER TOP ASSEMBLY
1945-P-5019	SLIMLINE WIRELESS BATTERY CHARGER
1945-P-7000	REFRACTION STAND POWER ADAPTOR
1952-P-1347	FISON TRANSFORMER KIT 120V (HOSPITAL PLUG)
2004-P-1021	LED HEADLAMP CO-AXIAL
2099-P-5010	MK2 HEADBAND ASSY
2199-P-5886	KEELER REGULAR FRAME – BLUE Z
2199-P-5894	KEELER REGULAR FRAME - RED
2199-P-6326	SPECTRA IRIS FRAME INSERT ASSY
3412-P-5047	VANTAGE+ DIGITAL CASE & INSERT
3412-P-7000	VANTAGE+ SOFT CASE & INSERT
3412-P-7002	SPECTRA+ SOFT CASE
EP39-22079	SMART PACK BATTERY



Certificate GB19/964765

SGS

The management system of

**Keeler Ltd**

Clewer Hill Road Windsor Berkshire SL4 4AA United Kingdom

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Design, Development and manufacture, distribution & service of Optometric and Ophthalmic medical devices and equipment.

This certificate is valid from 23 March 2023 until 23 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 09 October 1995

*Jonathan M. Hall*

Authorised by  
Jonathan Hall  
Global Head - Certification Services

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