

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:	Loupes or Surgical binoculars and Frames, reusable (See below Product Schedule)
EC Product Classification:	Class I, Annex IX, Rule 1
GMDN:	46786 Type P- Surgical Binoculars, reusable A pair of lenses intended to be mounted onto a surgeon's spectacles to function as small telescope and provide a magnified image of the visual field during patient examination or surgical intervention. Also known as a surgical loupe, it may be mounted onto the spectacle frames and positioned in front of the spectacle lenses or attached directly onto each of the spectacle lenses. It may also be connected to an external light source or a head-worn light for visual field illumination. This is a reusable device. 32036 - Headband, reusable A device designed to be worn on the head of a healthcare provider for the mounting of another device, most commonly a head-worn light or a binocular indirect ophthalmoscope (BIO), so that the mounted device will remain directed in the user's line of vision despite head movement. It is typically adjustable for a custom fit. This is a reusable device.

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:	• 93/42/EEC Medical Device Directive • EU 2015/863 Restriction of Hazardous Substances (RoHS 3) • 2013/172/EU Unique Device Identification (UDI) • 2012/19/EU The Waste Electrical and Electronic Equipment (WEEE) Directive • MEDDEV 2.7/1 Rev. 4
Applied Standards:	• BS EN ISO 13485:2016 • BS EN ISO 14971:2012 • BS EN 15223-1:2016 • BS EN ISO 15004-1:2009 • BS EN ISO 9022-2:2015 • BS EN ISO 9022-3:2015 • BS EN ISO 1639:2009 • BS EN ISO 10993-1: 2009
Notified Body:	SGS Belgium NV SGS House, Noorderlaan – 87, Antwerp, 2030 Belgium +32 3 545 44 00 https://www.sgs.be/en/

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

	Notified Body Number: 1639
CE Certificate Number:	Class I Self-Certified
Date of Issuance of Original CE Certificate:	N/A

DofC Reference to Tech File: DofC 05

Rev: 10

Signed: 

Arminster Purewal

Date: 06 Aug 2020

Regulatory Affairs Manager

Product Schedule:
Loupes or Surgical Binoculars and Frames, reusable

GMDN 46786 Type P		
Surgical Binoculars, reusable – SuperVu Galilean Loupe		
Part Number	Description	Product Classification
2112-P-1000	SUPERVU 2.0 x 34CM GALILEAN LOUPE	I
2112-P-1001	SUPERVU 2.0 x 46CM GALILEAN LOUPE	I
2112-P-1002	SUPERVU 2.0 x 34CM GALILEAN LOUPE	I
2112-P-1003	SUPERVU 2.0 x 46CM GALILEAN LOUPE	I
2112-P-1006	SUPERVU 2.5 x 34CM GALILEAN LOUPE	I
2112-P-1008	SUPERVU 2.5 x 46CM GALILEAN LOUPE	I
2112-P-1009	SUPERVU 2.5 x 50CM GALILEAN LOUPE	I
2112-P-1010	SUPERVU 2.5 x 34CM GALILEAN LOUPE	I
2112-P-1011	SUPERVU 2.5 x 42CM GALILEAN LOUPE	I
2112-P-1012	SUPERVU 2.5 x 46CM GALILEAN LOUPE	I
2112-P-1013	SUPERVU 2.5 x 50CM GALILEAN LOUPE	I
2112-P-1018	SUPERVU 3.0 x 34CM GALILEAN LOUPE	I
2112-P-1019	SUPERVU 3.0 x 42CM GALILEAN LOUPE	I
2112-P-1020	SUPERVU 3.0 x 46CM GALILEAN LOUPE	I
2112-P-1021	SUPERVU 3.0 x 50CM GALILEAN LOUPE	I
2112-P-1022	SUPERVU 3.0 x 34CM GALILEAN LOUPE	I
2112-P-1023	SUPERVU 3.0 x 42CM GALILEAN LOUPE	I
2112-P-1024	SUPERVU 3.0 x 46CM GALILEAN LOUPE	I
2112-P-1025	SUPERVU 3.0 x 50CM GALILEAN LOUPE	I

GMDN 46786 Type P		
Surgical Binoculars, reusable – SuperVu Galilean Hi-Res Loupe		
Part Number	Description	Product Classification
2112-P-1050	SUPERVU 3.0 x 34CM HI-RES GALILEAN LOUPE	I
2112-P-1051	SUPERVU 3.0 x 42CM HI-RES GALILEAN LOUPE	I
2112-P-1052	SUPERVU 3.0 x 46CM HI-RES GALILEAN LOUPE	I
2112-P-1053	SUPERVU 3.0 x 50CM HI-RES GALILEAN LOUPE	I

GMDN 46786 Type P		
Surgical Binoculars, reusable – Galilean Mini-Loupe		
Part Number	Description	Product Classification
2112-P-1064	2.5 x 34CM GALILEAN MINI-LOUPE	I
2112-P-1065	2.5 x 42CM GALILEAN MINI-LOUPE	I
2112-P-1066	2.5 x 46CM GALILEAN MINI-LOUPE	I
2112-P-1067	2.5 x 50CM GALILEAN MINI-LOUPE	I

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2112-P-2247	2.5 x 34CM GALILEAN MINI-LOUPE	I
2112-P-2248	2.5 x 42CM GALILEAN MINI-LOUPE	I
2112-P-2249	2.5 x 46CM GALILEAN MINI-LOUPE	I
2112-P-2250	2.5 x 50CM GALILEAN MINI-LOUPE	I

GMDN 46786 Type P		
Surgical Binoculars, reusable – XL Advantage Loupe		
Part Number	Description	Product Classification
2113-P-2000	2.5 x 34CM XL ADVANTAGE LOUPE	I
2113-P-2001	2.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-2002	2.5 x 46CM XL ADVANTAGE LOUPE	I
2113-P-2003	2.5 x 50CM XL ADVANTAGE LOUPE	I
2113-P-2004	3.5 x 34CM XL ADVANTAGE LOUPE	I
2113-P-2005	3.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-2006	3.5 x 46CM XL ADVANTAGE LOUPE	I
2113-P-2007	3.5 x 50CM XL ADVANTAGE LOUPE	I
2113-P-2008	4.5 x 34CM XL ADVANTAGE LOUPE	I
2113-P-2009	4.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-2010	4.5 x 46CM XL ADVANTAGE LOUPE	I
2113-P-2011	4.5 x 50CM XL ADVANTAGE LOUPE	I
2113-P-2012	5.5 x 34CM XL ADVANTAGE LOUPE	I
2113-P-2013	5.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-2014	5.5 x 46CM XL ADVANTAGE LOUPE	I
2113-P-2015	5.5 x 50CM XL ADVANTAGE LOUPE	I
2113-P-6010	4.5 x 46CM XL ADVANTAGE LOUPE ON BAR	I
2113-P-6011	4.5 x 50CM XL ADVANTAGE LOUPE ON BAR	I
2113-P-6012	5.5 x 34CM XL ADVANTAGE LOUPE ON BAR	I
2113-P-6021	3.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-6022	3.5 x 46CM XL ADVANTAGE LOUPE	I
2113-P-6025	4.5 x 42CM XL ADVANTAGE LOUPE	I
2113-P-6029	5.5 x 42CM XL ADVANTAGE LOUPE	I

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GMDN 32036		
Headband		
Part Number	Description	Product Classification
2199-P-7259	HEADBAND & HINGE FOR LOUPES	I

GMDN 32036		
Frames		
Part Number	Description	Product Classification
2199-P-1500	MATT BLACK REGULAR FRAME IN CARTON	I
2199-P-1519	BLUEZ REGULAR FRAME IN CARTON	I
2199-P-1527	RED REGULAR FRAME IN CARTON	I
2199-P-1543	MATT BLACK LT FRAME IN CARTON	I
2199-P-1551	BLUEZ LT FRAME IN CARTON	I
2199-P-1578	RED LT FRAME IN CARTON	I
2199-P-1682	SPECTRA + MATT BLACK REGULAR FRAME	I
2199-P-1690	SPECTRA + BLUEZ REGULAR FRAME	I
2199-P-1703	SPECTRA + RED REGULAR FRAME	I
2199-P-1738	SPECTRA + MATT BLACK LT FRAME	I
2199-P-1746	SPECTRA + BLUEZ LT FRAME	I
2199-P-1754	SPECTRA + RED LT FRAME	I
2199-P-1982	BLACK SMALL REGULAR FRAME IN CASE	I
2199-P-1983	BLUEZ SMALL REGULAR FRAME IN CASE	I
2199-P-1984	RED SMALL REGULAR FRAME IN CASE	I
2199-P-6330	SPECTRA IRIS BLACK REGULAR FRAME	I
2199-P-6333	SPECTRA IRIS BLUE REGULAR FRAME	I
2199-P-6336	SPECTRA IRIS RED REGULAR FRAME	I

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Accessories – Loupes	
Part Number	Description
2199-P-7216	LOUPE FLIP LEVER (PACK OF 7)

Accessories – Frames	
Part Number	Description
2199-P-7574	5 PROTECTIVE SHIELDS - REGULAR

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