

	EC Declaration of Conformity- Loupes	Revision: 05
		Review Date: 04/12/2019


Manufacturer: Keeler Ltd.
Address: Clewer Hill Road., Windsor, Berkshire, SL4 4AA,
 United Kingdom
Device Name: Loupes or Surgical binoculars, reusable
Device Classification: Class I
GMDN Classification Code(s) 32692 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/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 **Signature:** 
Position: Senior Regulatory Affairs Officer **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

Galilean Mini-Loupe

Description	Part number
2.5 Magnification x 34cm Working Distance	2112-P-1064
2.5 Magnification x 42cm Working Distance	2112-P-1065
2.5 Magnification x 46cm Working Distance	2112-P-1066
2.5 Magnification x 50cm Working Distance	2112-P-1067

SuperVu Galilean Loupe

Description	Part number
2.0 Magnification x 34cm Working Distance	2112-P-1000
2.0 Magnification x 34cm Working Distance	2112-P-1002
2.0 Magnification x 46cm Working Distance	2112-P-1001
2.0 Magnification x 46cm Working Distance	2112-P-1003
2.5 Magnification x 34cm Working Distance	2112-P-1006
2.5 Magnification x 34cm Working Distance	2112-P-1010
2.5 Magnification x 42cm Working Distance	2112-P-1007
2.5 Magnification x 42cm Working Distance	2112-P-1011
2.5 Magnification x 46cm Working Distance	2112-P-1008
2.5 Magnification x 46cm Working Distance	2112-P-1012
2.5 Magnification x 50cm Working Distance	2112-P-1009
2.5 Magnification x 50cm Working Distance	2112-P-1013
3.0 Magnification x 34cm Working Distance	2112-P-1018
3.0 Magnification x 34cm Working Distance	2112-P-1022
3.0 Magnification x 42cm Working Distance	2112-P-1019
3.0 Magnification x 42cm Working Distance	2112-P-1023
3.0 Magnification x 46cm Working Distance	2112-P-1020
3.0 Magnification x 46cm Working Distance	2112-P-1024
3.0 Magnification x 50cm Working Distance	2112-P-1021
3.0 Magnification x 50cm Working Distance	2112-P-1025

SuperVu Galilean Hi-Res Loupe

Description	Part number
3.0 Magnification x 34cm Working Distance	2112-P-1050
3.0 Magnification x 42cm Working Distance	2112-P-1051
3.0 Magnification x 46cm Working Distance	2112-P-1052
3.0 Magnification x 50cm Working Distance	2112-P-1053

XL Advantage Loupe

Description	Part number
3.5 Magnification x 34cm Working Distance	2113-P-2000
3.5 Magnification x 42cm Working Distance	2113-P-2001
3.5 Magnification x 46cm Working Distance	2113-P-2002
3.5 Magnification x 50cm Working Distance	2113-P-2003
3.5 Magnification x 34cm Working Distance	2113-P-2004
3.5 Magnification x 42cm Working Distance	2113-P-2005
3.5 Magnification x 46cm Working Distance	2113-P-2006
3.5 Magnification x 50cm Working Distance	2113-P-2007
4.5 Magnification x 34cm Working Distance	2113-P-2008
4.5 Magnification x 42cm Working Distance	2113-P-2009
4.5 Magnification x 46cm Working Distance	2113-P-2010
4.5 Magnification x 50cm Working Distance	2113-P-2011
5.5 Magnification x 34cm Working Distance	2113-P-2012
5.5 Magnification x 42cm Working Distance	2113-P-2013
5.5 Magnification x 46cm Working Distance	2113-P-2014
5.5 Magnification x 50cm Working Distance	2113-P-2015

Accessories

Description	Part number
SuperVu Protective Caps	2112-P-8049
SuperVu +1D Near Distance Caps	2112-P-8057
Hi Res Plano Protective Cap	2112-P-8065

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Hi Res + 1D Protective Cap	2112-P-8073
Loupe Salesman Set	2112-P-8102
XL Advantage Protective Caps	2113-P-7000
XL Advantage +1D Near Distance Caps	2113-P-7001