

EC DECLARATION OF CONFORMITY

Manufacturer: Keeler Ltd
Address: Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK
Device Name: Keeler Slit Lamp (H-Series)
Device Classification: Class I
GMDN Classification: 32697

Variants:

Slit Lamp 40H, Standard Set complete with Table Top	3020-P-2000
Slit Lamp 40H Digital, complete with Refraction Stand	3020-P-2001
Slit Lamp 40H, Refraction Unit Set	3020-P-2003
Slit Lamp 40H Digital, complete with Table Top	3020-P-2004
Slit Lamp 40H LED, Refraction Unit Set	3020-P-2006
Slit Lamp 40H LED, Standard Set complete with Table Top	3020-P-2007
Slit Lamp 40H Digital, complete with USA Refraction Stand	3020-P-2014
Slit Lamp 40H Digital Ready, complete with Refraction Stand	3020-P-2016
Slit Lamp 40H Digital Ready, complete with USA Refraction Stand	3020-P-2018

Accessories:

Spare Bulb	1030-P-7152
Spare Bulb	1030-P-7160
Volk Digital Lens Set	2105-L-2010
Tonometer R-Type	2414-P-2040
Tonometer T-Type	2414-P-2030
DSL User Instruction CD	2415-P-7028
Base Assembly	3020-P-5007
Chinrest Assembly	3020-P-5036
Mains Cable – Brazil	3020-P-7007
Mains Cable – Japan	3020-P-7008
Power Supply to Slit Lamp Base Cable	3020-P-7011
Refraction Stand Cable kit	3020-P-7014
Mains Cable – USA	3020-P-7016
Mains Cable – Australia	3020-P-7022
Mains Cable – China	3020-P-7023
USB A to USB Mini B 0.5m Cable	3020-P-7028
USB 3A to USB 3 Micro B (3m)	3020-P-7029
Keeler Kapture Lite Licence	3020-P-7036
Keeler Kapture Lite Video Licence	3020-P-7037
Keeler Kapture Digital Licence	3020-P-7038

Keeler

Ophthalmic Instruments

Keeler Kapture Digital Pro Licence	3020-P-7039
Keeler FA Licence	3020-P-7040
Chinrest Papers	3104-L-8200
Chinrest Papers – Single (pk 500)	3104-L-8201
Joystick Rubber	EP39-70369
DSL Illumination Projection Mirror - Long	EP39-80052
Linear Gear Rack	EP39-80173
Linear Gear Rack Cover	EP39-80174
DSL Splash Guard	EP39-80242
DSL Test/Setting Bar	EP39-80243
DSL Illumination Projection Mirror - Small	EP39-80250
DSL Dust Cover	EP39-80273
DSL Table Template	EP39-80324
DSL Digital X-Y Pad	EP39-80364
DSL Digital Left/ Right Label	EP39-80365
Mains Cable – EU	MIS138
Mains Cable – UK	MIS100

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.

This declaration is made on the basis of:

- i. Quality Management System Certificate No: LRQ 0943149/A Issued by the Lloyd's Register Quality Assurance, Notified Body (No: 0088) in accordance with the procedure set out in Annex II Section 3 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: Phil Burridge

Signature: 

Position: Senior Quality Engineer
Keeler Ltd

Date: 20/2/2014