

EC Declaration of Conformity to: Medical Device Regulation (MDR) 2017/745

Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
SRN:	GB-MF-000009031
Manufacturing Site(s):	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
EU Authorised Representative:	Visiometrics, S.L., Vinyals, 131 08221 Terrassa, Spain
SRN:	ES-AR-000001559
Swiss Authorised Representative:	Medicel AG Dornierstrasse 11 CH-9423 Altenrhein Switzerland
Device Description/Family:	Keeler Slit Lamps (See attached Product Schedule)
Basic UDI-DI:	50552727SLITLAMPSRG
EC Product Classification:	Class I -Self certified, Annex VIII, Rule 10 under MDR 2017/745
EC Conformity Assessment:	Annex II and III Technical Documentation + Annex IV Declaration of Conformity
Intended Purpose	The Desktop Slit Lamp is an AC-powered slit lamp biomicroscope that is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is also used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segment. The lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment of the human eye, which includes the eyelid, sclera, conjunctiva, iris, natural crystalline lens and cornea. The examination with a binocular slit lamp gives a stereoscopic enlarged image of the eye structures in detail, enabling the health practitioner to make an anatomical diagnosis for a variety of eye conditions.
GMDN Code:	35148 – Ophthalmic slit lamp, examination An electrically-powered, ophthalmic, binocular microscope designed to examine the interior anatomy of the eye (anterior and posterior surfaces) by viewing through the iris. It produces a narrow slit of powerful light which is projected into the eye, and resulting light reflections are detected obliquely with a travelling microscope to enable observation of the internal ocular surfaces. It is used to perform a variety of measurements [e.g., intraocular pressure (IOP) or tonometry, corneal thickness, anterior chamber depth] and to evaluate symptoms (e.g., eye itchiness, grittiness, pain, dry eyes, photophobia, and reduced visual acuity).
EMDN Code:	Z12120108 – Slit lamps

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 Medical Device Regulation (MDR) 2017/745 of 5 April 2017 as amended, concerning medical devices and the applicable union legislation identified below.

Applied Directives:	• Medical Device Regulation (MDR) - EU 2017/745 • Unique Device Identification (UDI) - 2013/172/EU • Restriction of Hazardous Substance (RoHS) 3 – 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive – 2012/19/EU • MEDDEV 2.7/1 Rev. 4
Applied Standards:	• BS EN ISO 13485:2016+A11:2021 • BS EN ISO 14971:2019+A11:2021 • BS EN ISO 10993-1:2020 • BS EN 60601-1:2006+A2:2021 • BS EN 60601-1-2:2015/A1:2021 • BS EN 62133-2:2017+A1:2021 • BS EN 62304:2006 +A1:2015 • BS EN ISO 10939:2017 • BS EN 60601-1-6:2010 +A2:2021 • BS EN 62366-1:2015 + A1:2020 • BS EN ISO 15004-1:2020 • BS EN ISO 15004-2:2007 • BS EN ISO 15223-1:2021 • BS EN ISO 20417:2021 • BS EN ISO 14155:2020 • BS EN 50419:2006 • BS EN 62471:2008
Notified Body:	SGS Belgium NV (NB# 1639) SGS House, Noorderlaan – 87, Antwerp, 2030 – Belgium +32 3 545 44 00 https://www.sgs.be/en/

DofC Reference to Tech File: DofC 02

Rev: 26

Signed: 

Date: 11 May 2023

Name: Arminder Purewal

Head of Global Regulatory & EMEA Quality Assurance, Keeler Ltd.

Product Schedule:

GMDN 35148			
Part Number	Product Description	Product Classification	GTIN
3020-P-2006	SLH 5XC LED REF	I	05055272711593
3020-P-2006-001	SLH 5XC LED REF STD - CHINA	I	05055272719476
3020-P-2007	SLH 5XC LED TBL	I	05055272711586
3020-P-2007-001	SLH 5XC LED - LARGE TABLE	I	05055272718394
3020-P-2009	SLH 5XC LED Di REF ST	I	05055272715164
3020-P-2010	SLH 5XC LED Di TBL	I	05055272715171
3020-P-2013	SLH 5XC LED TBL USA	I	05055272711784
3020-P-2015	SLH 5XC LED Di TBL USA	I	05055272715195
3020-P-2019	SLH 5XC LED DiR REF	I	05055272715201
3020-P-2020	SLH 5XC LED DiR TBL	I	05055272715218
3020-P-2021	SLH 5XC LED DiR TBL USA	I	05055272715225
3020-P-2023	SLZ 3XP REF	I	05055272715232
3020-P-2023-003	SLZ 3XP REF (WHITE)	I	05055272718479
3020-P-2024	SLZ 3XP TBL	I	05055272715249
3020-P-2025	SLZ 3XP TBL USA	I	05055272715256
3020-P-2026	SLZ 3XP Di REF	I	05055272715263
3020-P-2027	SLZ 3XP Di TBL	I	05055272715270
3020-P-2028	SLZ 3XP Di TBL USA	I	05055272715287
3020-P-2029	SLZ 3XP DiR REF	I	05055272715294
3020-P-2030	SLZ 3XP DiR TBL	I	05055272715300
3020-P-2031	SLZ 3XP DiR TBL USA	I	05055272715317
3020-P-2032	SLZ 5XP REF	I	05055272715324
3020-P-2033	SLZ 5XP TBL	I	05055272715331
3020-P-2034	SLZ 5XP TBL USA	I	05055272715348
3020-P-2035	SLZ 5XP Di REF	I	05055272715355
3020-P-2036	SLZ 5XP Di TBL	I	05055272715362
3020-P-2037	SLZ 5XP Di TBL USA	I	05055272715379
3020-P-2038	SLZ 5XP DiR REF	I	05055272715386
3020-P-2039	SLZ 5XP DiR TBL	I	05055272715393
3020-P-2040	SLZ 5XP DiR TBL USA	I	05055272715409
3020-P-2041	SLZ 3XC REF	I	05055272715416
3020-P-2042	SLZ 3XC TBL	I	05055272715423
3020-P-2043	SLZ 3XC TBL USA	I	05055272715430
3020-P-2044	SLZ 3XC Di REF	I	05055272715447
3020-P-2045	SLZ 3XC Di TBL	I	05055272715454
3020-P-2046	SLZ 3XC Di TBL USA	I	05055272715461
3020-P-2047	SLZ 3XC DiR REF	I	05055272715478
3020-P-2048	SLZ 3XC DiR TBL	I	05055272715485
3020-P-2049	SLZ 3XC DiR TBL USA	I	05055272715492
3020-P-2050	SLZ 5XC REF	I	05055272715508
3020-P-2051	SLZ 5XC TBL	I	05055272715515
3020-P-2052	SLZ 5XC TBL USA	I	05055272715522
3020-P-2053	SLZ 5XC Di REF	I	05055272715539
3020-P-2054	SLZ 5XC Di TBL	I	05055272715546
3020-P-2055	SLZ 5XC Di TBL USA	I	05055272715553
3020-P-2056	SLZ 5XC DiR REF	I	05055272715560
3020-P-2057	SLZ 5XC DiR TBL	I	05055272715577

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3020-P-2058	SLZ 5XC DiR TBL USA	I	05055272715584
3020-P-2059	SLH 5XC LED TBL VALON	I	05055272715591
3020-P-2070	SLH 5XC LED REF OEM	I	05055272715645
3020-P-2077	SLZ 3XC REF WHT	I	05055272716857
3020-P-2078	SLZ 3XC TBL WHT	I	05055272716864
3020-P-2079	SLZ 5XC REF WHT	I	05055272716871
3020-P-2080	SLZ 5XC TBL WHT	I	05055272716826
3020-P-2081	SLH 5XC LED - PLATE SYSTEM	I	05055272717236
3020-P-2082	SLH 5XC LED Di - PLATE SYSTEM	I	05055272718257
3020-P-2083	SLH 5XC LED DiR - PLATE SYSTEM	I	05055272718264
3020-P-2084	SLZ 5XC LED - PLATE SYSTEM	I	05055272718271
3020-P-2085	SLZ 5XC LED Di - PLATE SYSTEM	I	05055272718288
3020-P-2086	SLZ 5XC LED DiR - PLATE SYSTEM	I	05055272718295
3020-P-2089	SLH 3XC LED - REF	I	05055272717113
3020-P-2090	SLH 3XC LED - TABLE	I	05055272717120
3020-P-2091	SLH 3XC LED TABLE USA	I	05055272718097
3020-P-2092	SLH 3XC LED Di - REF	I	05055272717137
3020-P-2093	SLH 3XC LED Di - TABLE	I	05055272717144
3020-P-2094	SLH 3XC LED Di TABLE USA	I	05055272718103
3020-P-2095	SLH 3XC LED DiR - REF	I	05055272717151
3020-P-2096	SLH 3XC LED DiR - TABLE	I	05055272717168
3020-P-2097	SLH 3XC LED DiR TABLE USA	I	05055272718110
3020-P-2098	SLH 3XP LED - REF	I	05055272717175
3020-P-2099	SLH 3XP LED - TABLE	I	05055272717182
3020-P-2101	SLH 3XP LED Di - REF	I	05055272717199
3020-P-2102	SLH 3XP LED Di - TABLE	I	05055272717205
3020-P-2104	SLH 3XP LED DiR - REF	I	05055272717212
3020-P-2105	SLH 3XP LED DiR - TABLE	I	05055272717229
3020-P-2108	SLZ 5XC Di REF - WHITE	I	05055272717298
3020-P-2109	SLZ 5XC Di TBL - WHITE	I	05055272719681
3020-P-2110	SLZ 5XP Di REF - WHITE	I	05055272720410
3020-P-2112	SLH 5XP LED Di REF (WHITE)	I	05055272718066
3020-P-2113	SLH 5XC LED REF (WHITE)	I	05055272718073
3020-P-2114	SLH 5XC LED TABLE (WHITE)	I	05055272718080
3020-P-2121	SLZ 5XP REF WHITE	I	05055272718950
3020-P-2123	SLZ 5XP DiR REF WHITE	I	05055272718967
3020-P-2124	SLZ 3XP Di REF WHITE	I	05055272719377
3020-P-2125	SLZ 5XC LED PLT SYS - WHITE	I	05055272718882
3020-P-2126	SLH 3XP LED REF WHITE	I	05055272719384
3020-P-2127	SLH 5XP LED REF GREY	I	05055272719193
3020-P-2128	SLH 5XP LED REF WHITE	I	05055272719391
3020-P-2129	SLH 3XP LED DiR REF WHITE	I	05055272719407
3020-P-2130	SLH 5XP LED DiR REF	I	05055272719414
3020-P-2131	SLH 5XP LED DiR REF WHITE	I	05055272719261
3020-P-2132	SLH 3XP LED Di REF WHITE	I	05055272719421
3020-P-2133	SLH 5XP LED Di REF	I	05055272719124
3020-P-2135	SLH 5XC LED - PLATE SYSTEM (WHITE)	I	05055272719278
3020-P-2136	SLZ 5XC DiR REF (WHITE)	I	05055272719483
3020-P-2137	SLZ 5XC DiR TABLE (WHITE)	I	05055272719490

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Part Number	Product Description	Product Classification	GTIN
3020-P-2138	SLH 5XC LED Di PLATE SYSTEM (WHITE)	I	05055272719506
3020-P-2139	SLH 3XC LED - PLATE SYSTEM	I	05055272719544
3020-P-2140	SLH 3XC LED Di - PLATE SYSTEM	I	05055272719636
3020-P-2141	SLH 3XC LED DiR - PLATE SYSTEM	I	05055272719643
3020-P-2142	SLZ 3XC LED - PLATE SYSTEM	I	05055272719551
3020-P-2143	SLZ 3XC LED DiR - PLATE SYSTEM	I	05055272719650
3020-P-2144	SLZ 3XC LED Di - PLATE SYSTEM	I	05055272719667
3020-P-2145	SL-B2 3XC SLIT LAMP	I	05055272720090
3020-P-2145-001	SL-B2 3XC SLIT LAMP	I	05055272720137
3020-P-2145-002	SL-B2 3XC SLIT LAMP	I	05055272720144
3020-P-2146	NIDEK SLH 5XC LED - PLATE SYSTEM	I	05055272720588
3020-P-2151	SLH 5XC LED DiR - PLATE SYSTEM (WHITE)	I	05055272720281
3020-P-2155-002	SL-B3 3XC SLIT LAMP (GEN)	I	05055272720199
3020-P-2160	MODULIGHT SLIT LAMP	I	05055272720298

Accessories			
Part Number	Product Description	Product Classification	GTIN
1030-P-7160	BULB	Accessory	05055272700580
1205-P-7012	KAPTURE SOFTWARE MEMORY STICK	Accessory	05055272718240
2199-P-7136	LENS CLOTH	Accessory	05055272705516
2207-P-1026	2x HALBERG TRIAL CLIPS IN CASE	Accessory	05055272706520
3020-P-2022	DSL DIGITAL CAMERA KIT	Accessory	05055272711692
3020-P-2147	KSL DIGITAL KONNECT CAMERA KIT	Accessory	05055272720656
3020-P-5007	BASE ASSEMBLY (TABLE-TOP VARIANT ONLY)	Accessory	05055272715676
3020-P-5031	DSL DIGITAL CAMERA ASSEMBLY	Accessory	05055272715683
3020-P-5036	CHINREST ASSEMBLY	Accessory	05055272715690
3020-P-5041	DSL TABLE ASSEMBLY - DIGITAL	Accessory	05055272715706
3020-P-5062	DSL TABLE ASSY - USA REFRACTION STAND	Accessory	05055272715737
3020-P-5063	DSL DIGITAL USA REFRACTION STAND ASSEMBLY	Accessory	05055272720076
3020-P-5121	12V PSU & DRAWER KIT	Accessory	05055272715782
3020-P-5131	DSL CAMERA ASSEMBLY - NO BRANDING	Accessory	05055272719612
3020-P-5151	SL CHINREST ASSEMBLY - PLT SYS	Accessory	05055272717250
3020-P-5179	SLH/SLZ LARGE TABLE TOP ASSEMBLY	Accessory	05055272718400
3020-P-5191	SLH PLATE SYSTEM CHINREST ASSY	Accessory	05055272719452
3020-P-5211	OCULUS/KEELER T/T ASSEMBLY - 12V	Accessory	05055272719032
3020-P-5332	SLITLAMP CAMERA - MODULIGHT	Accessory	05055272720649
3020-P-7000	MULTI VOLTAGE TABLE LEG ASSEMBLY	Accessory	05055272715812
3020-P-7007	MAINS CABLES - BRAZIL	Accessory	05055272715843
3020-P-7008	MAINS CABLES - JAPAN	Accessory	05055272715850
3020-P-7011	POWER SUPPLY TO SLIT LAMP BASE CABLE (TABLE-TOP VARIANT ONLY)	Accessory	05055272715874
3020-P-7013	DSL REFRACTION CABLE (XY - BULB)	Accessory	05055272715898
3020-P-7016	MAINS CABLES - NORTH AMERICA	Accessory	05055272715911
3020-P-7017	REFRACTION STAND PSU & SKT KIT	Accessory	05055272715928

Accessories			
Part Number	Product Description	Product Classification	GTIN
3020-P-7020	LED REFRACTION STAND ACCESSORY KIT	Accessory	05055272715935
3020-P-7020-003	SLH LED REF ACCESSORY KIT - WHITE	Accessory	05055272719292
3020-P-7021	LED TABLE TOP ACCESSORY KIT	Accessory	05055272715942
3020-P-7021-003	SLH LED TABLE ACCESSORY KIT (WHITE)	Accessory	05055272719438
3020-P-7026	DSL DIGITAL TABLE ACCESSORY KIT	Accessory	05055272715966
3020-P-7032	SLIT LAMP USA REFR STAND KIT	Accessory	05055272715973
3020-P-7036	KEELER KAPTURE LITE LICENCE	Accessory	05055272720526
3020-P-7037	KAPTURE VIDEO LICENCE	Accessory	05055272720533
3020-P-7038	KEELER KAPTURE DIGITAL LICENCE	Accessory	05055272720540
3020-P-7039	KEELER KAPTURE DIGITAL PRO LICENCE	Accessory	05055272720557
3020-P-7042	UPGRADE KAPTURE LITE TO DIGITAL SOFTWARE	Accessory	05055272718011
3020-P-7045	KAPTURE VIEW SOFTWARE	Accessory	05055272718028
3020-P-7046	KAPTURE VIEW PLUS SOFTWARE	Accessory	05055272718035
3020-P-7051	DSL DIGITAL LED REFRACTION STAND ACCESSORY KIT	Accessory	05055272715997
3020-P-7051-003	SLH LED Di REF ACCESSORY KIT - WHITE	Accessory	05055272718318
3020-P-7052	TABLE ACCESSORY KIT DIGITAL	Accessory	05055272716000
3020-P-7055	Z-TYPE DSL REFRACTION STAND ACCESSORY KIT	Accessory	05055272716239
3020-P-7055-003	Z-TYPE REFRACTION STAND ACCESSORY KIT	Accessory	05055272716918
3020-P-7056	Z-TYPE DSL TABLE TOP ACCESSORY KIT	Accessory	05055272716109
3020-P-7056-003	Z-TYPE TABLE TOP ACCESSORY KIT	Accessory	05055272716833
3020-P-7057	Z-TYPE DSL DIGITAL REFRACTION STAND ACCESSORY KIT	Accessory	05055272716246
3020-P-7057-003	SLZ Di REF STD ACCESSORY KIT - WHITE	Accessory	05055272717274
3020-P-7058	Z-TYPE DSL DIGITAL TABLE TOP ACCESSORY KIT	Accessory	05055272716253
3020-P-7058-003	SLZ Di TBL TOP ACCESSORY KIT - WHITE	Accessory	05055272717281
3020-P-7061	DIELECTRIC PROJECTION MIRROR KIT	Accessory	05055272716024
3020-P-7065	OEM ACCESSORY KIT	Accessory	05055272716055
3020-P-7070	VALON ACCESSORY KIT 1	Accessory	05055272716086
3020-P-7081	SLH/SLZ MOUNTING PLATE SYSTEM	Accessory	05055272717243
3020-P-7082	DSL/ZSL LARGE TABLE IN CARTON	Accessory	05055272716932
3020-P-7084	QUANTEL DSL ACCESSORY KIT	Accessory	05055272716819
3020-P-7086	SL CHINREST & MOUNTING PLATE SYSTEM	Accessory	05055272719285
3020-P-7100	SLH CHINREST MOUNTING PLATE SYSTEM	Accessory	05055272719254
3020-P-7105	EYEPIECE WITH RETICULE	Accessory	05055272719308
3020-P-7115	LUMENIS SLIT LAMP CAMERA - WHITE	Accessory	05055272720168
3020-P-7126	NIDEK SLH ACCESSORY KIT	Accessory	05055272720595
3020-P-7145	KEELER KONNECT IMAGING SOFTWARE (INSTALL PROGRAMME USB + LICENCE USB KEY)	Accessory	05055272720618
3020-P-7150	KSL KL (P) TABLETOP & LEG KIT	Accessory	05055272720632
3020-P-7151	KEELER KONNECT PACs LICENSE (LICENSE USB)	Accessory	05055272720625
3104-L-8201	CHIN REST PAPERS	Accessory	05055272708074
EP39-80273	DUST COVER	Accessory	05055272712255