

DESTINATION: VIETNAM.

EC DECLARATION OF CONFORMITY

Manufacturer: Keeler Ltd.

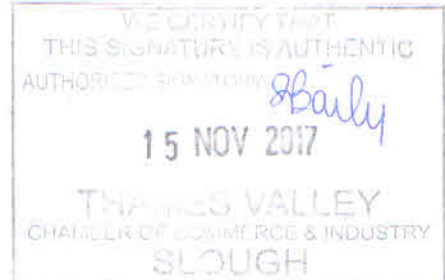
Address: Clewer Hill Rd., Windsor, Berkshire, SL4 4AA

Device Name(s): a. Ophthalmoscope, battery powered
b. Ophthalmoscope, line powered Susan Baily
c. Retinoscope, battery powered Authorized Signatory
d. Retinoscope, line powered
e. Otoscope, direct



Device Classification: Class I

GMDN Classification Code(s)
a. 46786 Type P
b. 46787 Type P
c. 32712 Type P
d. 46784 Type P
e. 12849 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/A 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: Phil Burridge

Signature:

Position: Senior Quality Engineer

Date: 30/10/2017

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



CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia..... Việt Nam
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) J. Allsop - ward... ký
has been signed by

3. với chức danh Cán bộ lãnh sự
acting in the capacity of

4. và con dấu của Bộ Ngoại giao Anh
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại London..... 6. ngày 29.11.2017
at the

7. Cơ quan cấp DSQ Việt Nam tại Anh
by

8. Số 4871..... và in-ten
No

Ký tên và đóng dấu
Signature and seal/stamp

Bà Thủ thiê nhất



[Handwritten signature]

Nguyễn Diệu Hà

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4. Bears the seal / stamp of est revêtu du sceau / timbre de Not applicable y está revestido del sello / timbre de	
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5. at à / en London	6. the le / el día 17 November 2017
7. by par / por Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs	
8. Number sous no / bajo el numero APO-622613	
9. Seal / stamp Sceau / timbre Sello / timbre 	10. Signature Signature Firma J. Allsop-Ward 

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Ophthalmoscopes

Description	Part number
2.8V POCKET OPHTHALMOSCOPE HEAD & BULB	1102-P-1033
POCKET SET 2.8V	1102-P-1041
JAZZ POCKET OPHTHALMOSCOPE 2.8V	1102-P-1092
JAZZ LED POCKET OPHTHALMOSCOPE 2.8V	1102-P-1105
JAZZ ULTRA POCKET OPHTHALMOSCOPE 2.8V	1102-P-1113
JAZZ ULTRA POCKET OPHTHALMOSCOPE 2.8V	1102-P-5018
KEELER POCKET LED OPHTH HEAD + LED	1102-P-5077
JAZZ ULTRA OPHTH LED HEAD	1102-P-5085
2.8V STANDARD OPHTH HEAD	1126-P-1002
3.5V STANDARD OPHTH HEAD & BULB	1126-P-1004
2.8V STANDARD OPHTH IN CASE	1126-P-1005
3.6V STANDARD OPHTH IN CASE	1126-P-1006
2.8V STANDARD LED OPHTH IN CASE	1126-P-1011
3.6V STANDARD LED OPHTH IN CASE	1126-P-1012
STANDARD LED OPHTH HEAD IN CART	1126-P-1013
STANDARD OPHTH + LED MODULE	1126-P-5005
2.8V PRACTITIONER OPHTH HEAD IN CARTON	1127-P-1002
3.5V PRACTITIONER OPHTH HEAD & BULB	1127-P-1004
2.8V PRACTITIONER OPHTH IN CASE	1127-P-1005
3.6V PRACTITIONER OPHTH IN CASE	1127-P-1006
2.8V PRACTITIONER LED OPHTH IN CASE	1127-P-1008
3.6V PRACTITIONER LED OPHTH IN CASE	1127-P-1009
PRACTITIONER LED HEAD IN CARTON	1127-P-1010
PRACTITIONER OPHTH + LED MODULE	1127-P-5003
2.8V PROFESSIONAL OPHTH IN CARTON	1128-P-1003
3.5V PROFESSIONAL OPHTH IN CARTON	1128-P-1004
2.8V PROFESSIONAL OPHTH IN CASE	1128-P-1013
3.6V PROFESSIONAL OPHTH IN CASE	1128-P-1014
2.8V PROFESSIONAL E OPHTHALMOSCOPE	1128-P-5003

3.6V PROFESSIONAL E OPHTHALMOSCOPE	1128-P-5004
PROFESSIONAL OPHTH + LED MODULE	1128-P-5008
SPECIALIST OPHTH + LED MODULE	1131-P-5228
2.8V SPECIALIST OPHTH HEAD & BULB	1132-P-1042
3.6V SPECIALIST OPHTH HEAD & BULB	1132-P-1050
2.8V SPECIALIST OPHTH IN CASE	1132-P-1149
3.6V SPECIALIST OPHTH (RECHARGEABLE)	1132-P-1157

Otoscopies

Description	Part number
2.8V POCKET OTO IN CASE	1503-P-1034
3.5V PRACTITIONER OTO HEAD & BULB	1513-P-1054
2.8V PRACTITIONER OTO	1513-P-1062
2.8V VISTA FIBRE-OPTIC OTO HEAD & BULB	1514-P-1064

Description	Part number
3.5V VISTA FIBRE-OPTIC HEAD & BULB	1514-P-1072
SLIMLINE 2.8V FIBRE-OPTIC OTO IN CASE	1514-P-1136
SLIMLINE 3.6V FIBRE-OPTIC OTO IN CASE	1514-P-1144
JAZZ LED POCKET OTOSCOPE 2.8V	1514-P-1160
JAZZ BULB OTOSCOPE SET	1514-P-1179
JAZZ ULTRA POCKET OTOSCOPE 2.8V	1514-P-1187
2.8V STANDARD OTO IN CARTON	1516-P-1025
3.5V VISTA STANDARD OTO HEAD & BULB	1516-P-1033
KEELER 2.8V STANDARD OTOSCOPE	1516-P-5069
KEELER 3.5V STANDARD OTOSCOPE	1516-P-5077
2.8V POCKET OTO HEAD	1517-P-1019
SLIMLINE 2.8V STANDARD OTO	1518-P-1001
SLIMLINE 3.6V STANDARD OTO	1518-P-1002
SLIMLINE 2.8V PRACTITIONER OTO	1519-P-1001

3.5V PRACTITIONER OTO IN CASE

1519-P-1002

Retinoscopes

Description

Part number

2.8V SPOT MAGNETIC RET	1302-P-1004
3.5V SPOT MAGNETIC RET	1302-P-1005
2.8V STREAK MAGNETIC RET	1302-P-1006
3.5V STREAK HEAD IN CARTON	1302-P-1007
2.8V PROFESSIONAL SPOT RETINOSCOPE IN CASE	1302-P-1008
3.6V PROFESSIONAL SPOT RETINOSCOPE IN CASE	1302-P-1009
2.8V PROFESSIONAL STREAK RETINOSCOPE IN CASE	1302-P-1010
3.6V PROFESSIONAL STREAK RETINOSCOPE IN CASE	1302-P-1011
PROFESSIONAL STREAK LED RETINOSCOPE HEAD	1302-P-1012
2.8V PROFESSIONAL STREAK LED RETINOSCOPE & CASE	1302-P-1013
3.6V PROFESSIONAL STREAK LED RETINOSCOPE & CASE	1302-P-1014
2.8V STREAK RET STUDENT SET (ITALY)	1427-P-1087

Desk Sets

Description

Part number

3.5V PRACTITIONER DESK SET	1729-P-1028
3.5V STANDARD DESK SET	1729-P-1029
3.5V PRACTITIONER/FIBRE-OPTIC DESK SET	1729-P-1030

Diagnostic Sets

Description

Part number

POCKET SET 2.8V	1702-P-1037
JAZZ POCKET DIAGNOSTIC SET 2.8V	1702-P-1088
JAZZ LED POCKET DIAGNOSTIC SET 2.8V	1702-P-1096
JAZZ ULTRA POCKET DIAGNOSTIC SET 2.8V	1702-P-1109
VISTA FIBRE-OPTIC SET DRY 2.8V HAL	1727-P-1009

SLIMLINE 2.8V STANDARD SET	1729-P-1018
SLIMLINE 2.8V PRACTITIONER DIAGNOSTIC SET	1729-P-1019
SLIMLINE 2.8V PRACTITIONER/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1020
SLIMLINE 3.6V STANDARD DIAGNOSTIC SET	1729-P-1022
SLIMLINE 3.6V PRACTITIONER DIAGNOSTIC SET	1729-P-1023
SLIMLINE 3.6V PRACTITIONER/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1024
SLIMLINE 2.8V PROFESSIONAL/FIBRE-OPTIC OTO SET	1729-P-1033
2.8V STANDARD/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1041

Ophthalmoscope/Retinoscope Sets

Description	Part number
SPECIALIST & COMBI RET SET	1427-P-1054
SLIMLINE 2.8V STREAK RET & PROFESSIONAL OPHTH	1427-P-1058
3.5V STREAK/PROFESSIONAL SET WITH 2 HANDLES	1427-P-1059
SLIMLINE 2.8V SPOT RET & PROFESSIONAL OPHTH	1427-P-1060
SLIMLINE 3.6V SPOT RET & PROFESSIONAL OPHTH	1427-P-1061
SLIMLINE 2.8V STREAK RET & SPECIALIST OPHTH	1427-P-1062

Ophthalmoscope/Retinoscope Sets

Description	Part number
SLIMLINE 3.6V STREAK RET & SPECIALIST OPHTH	1427-P-1063
SLIMLINE 2.8V SPOT RET & SPECIALIST OPHTH	1427-P-1064
SLIMLINE 3.6V SPOT RET & SPECIALIST OPHTH	1427-P-1065
3.5V MAGNETIC STREAK RET/PROFESSIONAL OPHTH & HANDLE	1427-P-1071
2.8V STREAK LED RETINOSCOPE & PROFESSIONAL OPHTHALMOSCOPE	1427-P-1101
3.6V STREAK LED RETINOSCOPE & PROFESSIONAL OPHTHALMOSCOPE	1427-P-1102
2.8V STREAK LED RETINOSCOPE & SPECIALIST OPHTHALMOSCOPE	1427-P-1103
3.6V STREAK LED RETINOSCOPE & SPECIALIST	1427-P-1104

OPHTHALMOSCOPE

3.6V STREAK LED RET & PROFESSIONAL OPHTH & 1 HANDLE 1427-P-1107

Student Sets

Description	Part number
PROFESSIONAL & COMBI RET STUDENT SET	1427-P-1053
PROFESSIONAL STUDENT KIT, SLIMLINE HANDLE (USA)	1427-P-1057
3.6V SPECIALIST/STREAK STUDENT SET	1427-P-1067
3.6V PROFESSIONAL STUDENT SET	1427-P-1068
AUSTRALIAN SPECIALIST SET	1427-P-1082
AUSTRALIAN SPECIALIST SET	1427-P-1083
STUDENT SET (SOUTH AMERICA)	1427-P-1085
2.8V SPOT RET STUDENT SET (ITALY)	1427-P-1086
2.8V STREAK OPHTH STUDENT SET (ITALY)	1427-P-1088
3.6V STREAK/PROFESSIONAL STUDENT SET (ESSILOR)	1427-P-1089
3.6V SPECIALIST/STREAK STUDENT SET (ESSILOR)	1427-P-1090
3.6V STREAK/PROF STUDENT SET (HOLLAND)	1427-P-1091
2.8V STUDENT SET (INDIA)	1427-P-1092
2.8V STUDENT SET (TAIWAN)	1427-P-1093

Description	Part number
3.6V STUDENT SET (TAIWAN)	1427-P-1094
3.6V STUDENT SET CW VOLK	1427-P-1095
US PROFESSIONAL LED STUDENT KIT	1427-P-1100
SPECIALIST & COMBI LED STUDENT SET	1427-P-1105
AUSTRALIAN LED SPECIALIST SET	1427-P-1108
AUSTRALIAN LED PROFESSIONAL SET	1427-P-1109
3.6V PROFESSIONAL LED STUDENT SET	1427-P-1110
2.8V LED STREAK RET & PROF SINGLE	1427-P-1113
3.6V SPECIALIST & COMBI LED ONLY STUDENT SET	1427-P-1116

3.6V PROFESSIONAL LED ONLY STUDENT SET	1427-P-1117
3.6V PROFESSIONAL STUDENT SET LED ONLY VOLK	1427-P-1118
3.6V SPECIALIST STUDENT SET LED ONLY VOLK	1427-P-1119
2.8V STK LED RET & PRACT OPHTH WITH 1 HANDLE	1427-P-1125

Veterinary Sets

Description	Part number
3.6V STANDARD VET DIAGNOSTIC SET	1729-P-1038
3.6V PRACTITIONER VET DIAGNOSTIC SET	1729-P-1039
3.5V STANDARD VET DESK SET	1729-P-1043
2.8V STANDARD VET DIAGNOSTIC SET	1729-P-1044
3.6V PRACTITIONER VET DESK SET	1729-P-1045
2.8V PRACTITIONER VET DIAGNOSTIC SET	1729-P-1047
2.8V STANDARD LED OPHTH / OTO DIAGNOSTIC SET	1729-P-1048
3.6V STANDARD LED OPHTH / OTO DIAGNOSTIC SET	1729-P-1049
2.8V PRACTITIONER LED OPHTH / OTO DIAGNOSTIC SET	1729-P-1050
3.6V PRACTITIONER LED OPHTH / OTO DIAGNOSTIC SET	1729-P-1051
2.8V STANDARD LED/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1052
2.8V PRACTITIONER LED/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1053
3.6V PRACTITIONER LED/FIBRE-OPTIC DIAGNOSTIC SET	1729-P-1054
3.6V STANDARD LED DESK SET	1729-P-1055
3.6V PRACTITIONER LED DESK SET	1729-P-1056
3.6V PRACTITIONER LED / FO DESK SET	1729-P-1057
3.6V CORDED STANDARD VET SET	1964-P-2013
3.6V CORDED PRACTITIONER VET SET	1964-P-2014

Accessories

Description	Part number
POCKET OPHTHALMOSCOPE LED ASSEMBLY	1011-P-5522
JAZZ OPHTHALMOSCOPE BULB	1011-P-5530

OPHTH LED ASSY	1011-P-5610
SPECIALIST LED ASSY	1011-P-5637
SPEC/VISTA HAL BULB 3.5V PKT2	1011-P-7034
SPEC/VISTA HAL BULB 2.8V PKT2	1011-P-7042
POCKET OPHTH HAL BULB 2.8V PKT2	1011-P-7050
STD/PRACT/PROF XE BULB 2.8V PKT2	1011-P-7106
JAZZ OPHTHALMOSCOPE BULB PKT2	1011-P-7202
STD/PRACT/PROF XE BULB 3.5V PKT2	1011-P-7114
JAZZ ULTRA OPHTHALMOSCOPE LED	1011-P-7122
VISTA/PROF STREAK BULB 2.8V PKT2	1013-P-7008
VISTA/PROF STREAK BULB 3.5V PKT2	1013-P-7009
PROF SPOT BULB 2.8V PKT2	1013-P-7010
PROF SPOT BULB 3.5V PKT2	1013-P-7011
POCKET OTOSCOPE LED ASSEMBLY	1015-P-5298
STD OTOSCOPE HAL BULB 3.5V PKT2	1015-P-7023
STD OTOSCOPE HAL BULB 2.8V PKT2	1015-P-7031
FO OTOSCOPE HAL BULB 3.5V PKT2	1015-P-7058
FO OTOSCOPE HAL BULB 2.8V PKT2	1015-P-7066
JAZZ ULTRA OTOSCOPE SPARE LED	1015-P-7074
STREAK RET LED BLISTER PACK	1305-P-7000
DYNAMIC TARGETS FOR RETINOSCOPE	1321-P-7021
BAG OF 500 DISPOSABLE SPECULUM NO.2	1501-P-5170
BAG OF 500 DISPOSABLE SPECULUM NO.4	1501-P-5189
BAG OF 500 NO.1 (2.5MM) SPECULA	1501-P-5197
BAG OF 500 NO.3 (4.5MM) SPECULA	1501-P-5218
BAG OF 100 NO.1 SPECULA (2.5MM)	1501-P-5306
BAG OF 100 NO.2 SPECULA (3.5MM)	1501-P-5314
BAG OF 100 NO.3 SPECULA (4.5MM)	1501-P-5322
BAG OF 100 NO.4 SPECULA (5.5MM)	1501-P-5330
MAG LENS/ATC FOR STD+PKT OTO	1501-P-7117
SPECULUM NO.1	1512-P-7008

SPECULUM NO.2	1512-P-7016
SPECULUM NO.3	1512-P-7024
SPECULUM NO.4	1512-P-7032
SPECULUM NO.5	1512-P-7040
VISTA AIR TIGHT CHAMBER-ATC MAC	1512-P-7067
AIRTIGHT CHAMBER/PNEUMATIC TESTING	1512-P-7083
TUBE OF DISPOSABLE SPECULA	1513-P-5020
DISPOSABLE SPECULA (NO ADAPTOR)	1513-P-7026
VIEWING LENS & MNT-VISTA OTO	1513-P-7034
KEELER POCKET FIBRE OPTIC OTOSCOPE HEAD	1514-P-5110
JAZZ ULTRA OTOSCOPE HEAD	1514-P-5137
FIBRE OPTIC/STANDARD INSUFFLATOR ADAPTOR	1514-P-7001
PNEUMATIC TESTING ADAPTER	1514-P-7028
JAZZ 2MM REUSABLE SPECULUM (PK of 10)	1514-P-7036
JAZZ 2.5MM REUSABLE SPECULUM (PK of 10)	1514-P-7044
JAZZ 3MM REUSABLE SPECULUM (PK of 10)	1514-P-7052
JAZZ 4MM REUSABLE SPECULUM (PK of 10)	1514-P-7060
JAZZ 5MM REUSABLE SPECULUM (PK of 10)	1514-P-7079
JAZZ 2MM SPECULUM (PK of 100)	1514-P-7087

Description	Part number
JAZZ 2.5MM SPECULUM (PK of 100)	1514-P-7095
JAZZ 3MM SPECULUM (PK of 100)	1514-P-7108
JAZZ 4MM SPECULUM (PK of 100)	1514-P-7116
JAZZ 5MM SPECULUM (PK of 100)	1514-P-7124
JAZZ 2.5MM/4.0MM DISPOSABLE SPECULUM (PK - 5 of EACH)	1514-P-7132
BULB EXTRACTOR	1599-P-7018
SET OF PERMANENT SPECULA	1599-P-7229
INSUFFLATOR BULB FOR ALL OTO	1599-P-7245
KEELER TORCH -WITH REPLACEBLE BATTERY	1602-P-1064

KEELER SILVER PENLIGHTS - PACK OF 6	1602-P-1072
PENLIGHT, SILVER	1602-P-1080
2.8V SLIMLINE HANDLE	1901-P-1101
POCKET HANDLE	1901-P-5356
POCKET HANDLE DRY CELL BOTTOM CAP	1901-P-5372
2.8V POCKET HANDLE	1901-P-5380
BLUE BASE CAP, 2.8V SLIMLINE HANDLE (AA)	1901-P-5444
RED BASE CAP, 3.6V SLIMLINE HANDLE (LITHIUM)	1901-P-5452
KEELER JAZZ HANDLE	1901-P-5460
JAZZ SHORT HANDLE ASSY	1901-P-5479
SLIMLINE HANDLE SLEEVE - PINK	1901-P-7028
SLIMLINE HANDLE SLEEVE - GREEN	1901-P-7036
SLIMLINE HANDLE SLEEVE - BLUE	1901-P-7044
SLIMLINE HANDLE SLEEVE - BLACK	1901-P-7052
SLIMLINE LITHIUM HANDLE	1911-P-1201
LITHIUM DUO CHARGER & 2 SLIMLINE HANDLES	1911-P-1228
SLIMLINE HANDLE & MINI CHARGER	1911-P-1236
3.5V LITHIUM HANDLE UPGRADE KIT	1919-P-7093
LITHIUM MINI CHARGER	1941-P-1341
LITHIUM DOUBLE CHARGER	1941-P-1368
LITHIUM DOUBLE CHARGER ONLY	1941-P-5289
LITHIUM MINI CHARGER ASSY	1941-P-5326
SPECULA DISPENSER UNIT	1964-P-2000
DOUBLE CORD HANDLE POWER SUPPLY	1964-P-2001
3.5V PRACTITIONER DIAGNOSTIC SET	1964-P-2002
3.5V STANDARD DIAGNOSTIC SET	1964-P-2003
3.5V PRACTITIONER FIBRE-OPTIC DIAGNOSTIC SET	1964-P-2004
SLIMLINE HANDLE SUB-ASSY	1999-P-5660
DOUBLE CHARGER WALL MOUNT KIT	1999-P-7308
2.8V TRANSILLUMINATOR IN CARTON	2903-P-7000
3.5V TRANSILLUMINATOR IN CARTON	2903-P-7001

Keeler

Ophthalmic Instruments

RUBBER HANDLE SLEEVE

EP29-05365

POWER SUPPLY

EP29-32777

3.6V LITHIUM BATTERY

EP39-18918