

EC Declaration of Conformity- K-LED II

Revision: 05
Review Date: 04/12/2019

Manufacturer: Keeler Ltd.

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

United Kingdom

Device Name: K-LED II

Device Classification: Class I

GMDN Classification Code(s) 31779

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:

- 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 Date: 04/12/2018

Officer

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QM05 Reference 1 DofC Template Issue 3

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Description	Part number
K-LED II, Double Charger & 2 Lithium Batteries	2004-P-1007
K-LED II, Double Charger & 1 Lithium Battery	2004-P-1008
K-LED II, Single Charger, 1 Lithium Battery & Case	2004-P-1012
K-LED II, Single Charger & 1 Lithium Battery	2004-P-1016
K-LED II, Co-Ax Double Charger & 2 Lithium Batteries	2004-P-1017
K-LED II, Co-Ax Double Charger & 1 Lithium Battery	2004-P-1018
K-LED II, Co-Ax Single Charger, 1 Lithium Battery & Case	2004-P-1019
K-LED II, Coaxial Bracket WO Headlamp	2004-P-5003
K-LED II, LED Headlamp Coaxial MKII	2004-P-5006

Accessories

Description	Part number
Rechargeable Battery	1919-P-5215
Double Charger	1941-P-5350
Lithium Battery Charger & Battery	1941-P-5385
Adaptor PD Bar	2001-P-7027
Carry Case	3412-P-7002
Yellow Filter Cap	EP39-52798