Keeler
Ophthalmic Instruments

EC DECLARATION OF CONFORMITY

Manufacturer:	Keeler Ltd	
Address:	Clewer Hill Road, Windsor, Berkshire, SL4 4AA	
Device Name:	Digital Keeler Applanation Tonometer (D-KAT)	
Variants:	Digital Keeler Applanation Tonometer (T-Type)	2414-P-2032
	Digital Keeler Applanation Tonometer (R-Type)	2414-P-2042
Accessories:	Keeler Applanation Prism	2414-P-5001
	Calibration arm assembly	2414-P-5005
	T type guide plate	2414-P-5032
	R type post	2414-P-5042
	D-KAT Luxury carrying case	3414-P-7010
Device Classification:	Class IIa	
GMDN Classification Code	16809	

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/B, Issued by the Lloyd's Register Quality Assurance Limited, Notified Body (No: 0088) in accordance with the procedure set out in Annex V 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 IIa 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: 4/3/2014

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