

EC Declaration of Conformity to: Medical Device Directive 93/42/EEC

Legal Manufacturer:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom
Manufacturing Site(s):	Cryo Mk II Console: Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA United Kingdom Probes Cryo II: Nu Perspectives Ltd, 9a, Stonefield Park, Martins Lane, Chilbolton SO20 6BL United Kingdom
EU Authorised Representative	Visiometrics, S.L., Vinyals, 131 08821 Terrassa, Spain
Device Description/Family:	Cryomatic MK II Cryosurgical System, Pencils and Accessories (See below Product Schedule)
EC Product Classification:	Class IIb, Annex IX, Rule 9
GMDN:	46052 – Ophthalmic Cryosurgical System, electronic An assembly of mains electricity (AC-powered) devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal during an ophthalmic surgical procedure. The system typically includes an electronic control unit which controls the flow of cryogen contained in a connected cylinder, dedicated cryogen-cooled hand-held applicators (probes) to apply the cold to the tissue, a foot-switch, and interconnections. It is commonly used for cryopexy for retinal detachment, cataract extraction, and to treat glaucoma, trichiasis, and retinopathy of prematurity (ROP)

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 Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices.

Applied Directives:	• Medical Device Directive - 93/42/EC • Restriction of Hazardous Substances (RoHS) - 2011/65/EU • Waste Electrical and Electronic Equipment (WEEE) Directive - 2013/172/EU • MEDDEV 2.7/1 Rev. 4
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Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) Website: www.keeler.co.uk
Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40

Applied Standards:	• BS EN 1041:2008 +A1:2013 • EN ISO 13485:2016 • EN ISO 15223-1:2016 • EN ISO 14971:2012 • EN ISO 10993-1:2009 • EN ISO 14155:2011 • EN ISO 15004-1:2009 • EN 62366-1:2015 • EN 50419:2006
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	• IEC 60601-1:2006+A12:2014 • IEC 60601-1-2:2014 • EN 60601-1-6:2010+A1:2015 • EN 62304:2006 +A1:2015 • EN ISO 17664:2004 • EN ISO 11737-1:2006 • EN ISO 11737-2:2009 • ISO 10993-7:2008 • ISO 14644-1:2015
Notified Body:	SGS Belgium NV SGS House Noorderlaan 87 Antwerp, 2030 Belgium +32 3 545 44 00 Notified Body Number: 1639
CE Certificate Number:	Annex II exc. Section 4 (EC Certificate No. GB20/965236, valid until 30 September 2022)
Date of Issuance of Original CE Certificate:	28 February 2020

DofC Reference to Tech File: DofC 10

Rev: 13

Signed: 

Arminder Purewal

Date: 19 Jan 2021

Head of Regulatory Affairs
and Quality Assurance,
Keeler Ltd

Product Schedule:
Cryomatic MK II Cryosurgical System, Pencils and Accessories

Part Number	Description	Product Classification
2509-P-1010	CRYOMATIC MKII SYSTEM	IIb
2509-P-8020	2.5MM STANDARD RETINAL PROBE CRYO II	IIb
2509-P-8021	2.5MM EXTENDED RETINAL PROBE CRYO II	IIb
2509-P-8022	2.5MM MID REACH RETINAL PROBE CRYO II	IIb
2509-P-8023	0.89MM INTRA VITREAL PROBE CRYO II	IIb
2509-P-8024	1.5MM CURVED CATARACT PROBE CRYO II	IIb
2509-P-8025	3MM GLAUCOMA PROBE CRYO II	IIb
2509-P-8026	4x10MM COLLINS TRICHIASIS PROBE CRYO II	IIb
2509-P-8030	CLASSIC RETINAL PROBE CRYO II	IIb

Accessories	
Part Number	Description
2508-P-7005	CRYOMASTER TROLLEY
2508-P-7015	PIN INDEX YOKE FOR E SIZE CO2 CYLINDER
2508-P-7016	ADAPTOR FOR F SIZE CO2 CYLINDER
2508-P-7017	PIN INDEX YOKE FOR E SIZE N2O CYLINDER
2508-P-7018	ADAPTOR FOR F SIZE N2O CYLINDER
2509-P-8007	CRYO HOSE ASSEMBLY REPAIR KIT
2509-P-8008	CRYO GAS COUPLING KIT
2509-P-8015	CRYOMATIC STERILISATION BOX
2508-P-8026	DISPOSABLE PROBE ADAPTOR
2509-P-8027	CRYOMATIC STEM NUT ASSEMBLY TOOL
2509-P-8028	CRYO II HOSE ASSY REPAIR KIT

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