EC Certificate Full Quality Assurance System: Certificate GB20/965236

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Keeler Cryomatic MKII Console & Pencils for use in ophthalmic surgery
Laser Indirect Ophthalmoscope (LIO)
for use in ophthalmic surgical procedures

Tonometers to aid diagnosis and measurement of intraocular pressures:
Pulsair Intellipuff – Non-Contact Tonometer
TonoCare – Non-Contact Tonometer
Pulsair Desk Top Tonometer
Keeler Digital Applanation Tonometer (D-KAT)
Keeler Digital Applanation Tonometer (D-KAT), Z Type

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 May 2021 until 23 March 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 10 September 1995

Certification is based on reports numbered GB/PC 240569

Authorised by

Global Medical Devices Head of Notified Body

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