EC Certificate Production Quality Assurance System: Certificate GB99/50841



The management system of

Malvern Medical Developments Ltd also trading as PB Medical Limited

Unit 10, Northbrook Close, Worcester, WR3 8BP, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 15 June 2017 until 18 May 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 May 2020 Issue 18. Certified since 16 August 1999

Certification is based on reports numbered GB/PC 08783

Authorised by



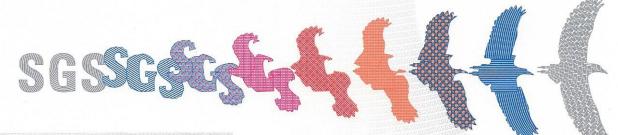
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EC Certificate Production Quality Assurance System: Certificate GB99/50841, continued

Malvern Medical Developments Ltd also trading as PB Medical Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 18

Detailed scope

Sterile:

Bladder and urodynamic catheters

Catheter sets

Accessories (extension lines, pump tube sets, anti back flow safety valve, voiding adaptor, set guard, Y connector, fir tree connectors, coloured manometer line)

Non-sterile: Gastrointestinal oesophageal catheters Anorectal manometry catheters

Annex V Sterility aspects only: Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Sterile saliva collection kit

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