

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

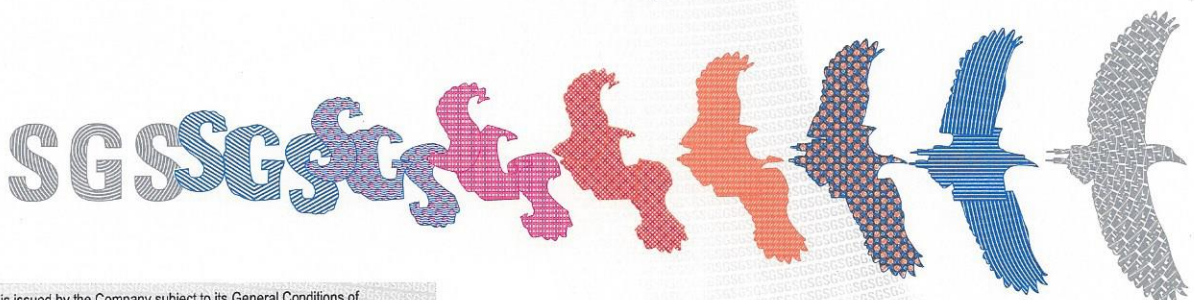
Authorised by

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Page 1 of 2





# 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.