EC Certificate Production Quality Assurance System: Certificate GB19/964512

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 24 May 2021 until 18 May 2023
and Remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 16 August 1999.

Certification is based on reports numbered GB/PC/ 08783

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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Malvern Medical Developments Ltd
also trading as PB Medical Limited

Directive 93/42/EEC

Issue 2

Detailed scope

Sterile:
Bladder, Anorectal Manometry and Urodynamic Catheters
Bladder and Urodynamic Catheter Sets and catheter Accessories
(extension lines, pump tube sets, 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.