

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

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design and manufacture of:

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)

Saliva collection kit

Non-sterile:

Gastrointestinal oesophageal catheters

Anorectal manometry catheters

This certificate is valid from 15 June 2017 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 16. Certified since 12 June 1998

Authorised by



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