Medical Device Full Quality Assurance System Certificate GB22/00000463

The management system of

Medchip Solutions Ltd

Chislehurst Business Centre 1 Bromley Lane Chislehurst Kent BR7 6LH United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products
SpiroConnect and GoSpiro hand-held, battery operated, turbine based spirometers.

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

This certificate is valid from 11 October 2022 until 11 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 11 October 2022
Certification is based on reports numbered GB/PC/231117

Authorised by
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Head of Approved Body 0120

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