Declaration of Conformity

for Spirometer SpiroConnect with SpiroConnect Data Manager (Windows PC Software)

UK Statutory Instruments 2002 No. 618: The Medical Devices Regulations 2002

The undersigned declares that the products described in this document meet the UK Regulation provisions that apply to them and the UKCA Mark may be affixed.

General Product Name:	SpiroConnect
Legal Manufacturer:	MedChip Solutions Limited Chislehurst Business Centre, 1 Bromley Lane, Chislehurst, Kent, BR7 6LH, United Kingdom
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The intended use of the SpiroConnect is to provide spirometry measurements used for the diagnosis of common respiratory diseases such as asthma and COPD in adults and children aged 3 and older. The SpiroConnect is intended to be used in doctors' offices, hospitals and clinics.
MDR Classification:	Class II(a)
UKCA Certificate Reference:	Medical Device Full Quality Assurance System Certificate GB22/00000463
UKCA Conformity Assessment Route:	UK MDR 2002 Requirements - Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002]
Approved Body	SGS United Kingdom Limited (0120) Rossmore Business Park Ellesmere Port Cheshire CH65 3EN

Name Dean Forster **Position** Operations Director

Signed Dean Forster **Date** 22/7/2025

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following UK Designated Standards[1] and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008 BS EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223:2016	Symbols for labelling in the medical devices
EN 60601-1:2006	General requirements for basic safety
EN 60601-1-2:2015	Electromagnetic compatibility;
EN ISO 26782:2009	Anaesthetic and respiratory equipment – spirometers intended for the measurement of time forced expired volumes in humans
EN 62304:2006	Medical device software — Software life-cycle processes
EN 301 489-17 v3.2.0 (Draft)	Electromagnetic Compatibility (EMC) standard for radio equipment and services
UK Statutory Instruments 2012 No. 3032	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012[2]
EU Regulation 207/2012[3]	Electronic Instructions for use of Medical Devices
Regulation 4J of the Medical Device Regulations 2002 [as amended] [UK MDR 2002]	Electronic Instructions for use of Medical Devices
Radio Equipment Regulations 2017: Great Britain	From: "Guidance on the regulations as they apply to equipment being supplied in or into Great Britain. May 2022" "The Radio Equipment Regulations 2017 implemented Directive 2014/53/EU on radio equipment. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU."
Directive 2014/53/EU	on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC. (The full text of the EU RED declaration of conformity is available at the following internet address: http://www.medchipsolutions.com/certificates.html)

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
SpiroConnect	Spirometer with Windows PC software.	13680

[1] THE DEPARTMENT OF HEALTH AND SOCIAL CARE NOTICE OF PUBLICATION 0034/21 of 1 January 2021 of references to standards for medical devices in support of the Medical Devices Regulations 2002 (S.I. 2002/618)

[2] On the EU this is Directive 2011/65/EU Restriction of the use of certain hazardous substances (RoHS)

[3] This is only revoked on 25/May/2025 according to MDR 2002 4.J.

Version History

Version	Compiled by	Date	Description
1 Draft 1	Dean Forster	13/7/2022	Initial DRAFT version for UK MDR 2002 / UKCA
1 Draft 2	Dean Forster	14/7/2022	Only designated standards used. Initial work on transition from EU Directives to UK Regulations.
1 Draft 3	Dean Forster	31/8/2022	Updated UKCA Conformity Assessment Route: UK MDR 2002 Requirements - Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to the Medical Devices Regulations 2002]
1	Dean Forster	13/2/2023	GoSpiro has its own certificate 006.048.001 as approved to 60601-1-11. UKCA Certificate GB22/00000463 added and issued.
1.1 D1	Dean Forster	8/6/2023	The MHRA Designated Standards list 1 January 2021 does not reference the BS version of standards, so neither do we. Added Regulation 4J of the Medical Device Regulations 2002 [as amended] [UK MDR 2002] Electronic Instructions for use of Medical Devices
1.1	Dean Forster	30/7/2024	Issued
1.2	Dean Forster	22/4/2025	Moved Approved Body Address to end of table and reformatted. Intended use harmonised with the exact wording of “001.029 Issue 2 SpiroConnect Intended Use”. Removed reference to the App.
1.3	Dean Forster	22/7/2025	Removed “002.048.001” from footer and filename. No other change.