Declaration of Conformity

for Spirometer SpiroConnect with SpiroConnect Data Manager (Windows PC)

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE 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:	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. Used in doctors' offices, hospitals, clinics.
MDD Classification:	Class II(a)
Notified Body:	SGS Belgium NV, Notified Body 1639, SGS House, Noorderlaan, 87 2030, Antwerp, Belgium
CE Certificate Reference:	EC Certificate Full Quality Assurance System. Certificate GB19/964555
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance in accordance with Annex II of the Medical Device Directive

Name Dean Forster **Position** Operations Director and Quality Manager

Signed  **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 European standards 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	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
BS EN ISO 15223:2016	Symbols for labelling in the medical devices
BS EN 60601-1:2006	General requirements for basic safety
BS EN 60601-1-2:2014	Electromagnetic compatibility;
BS EN ISO 26782:2009	Anaesthetic and respiratory equipment – spirometers intended for the measurement of time forced expired volumes in humans
BS 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
Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
Regulation 207/2012	Electronic Instructions for use of Medical Devices
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 PC software.	13680

Version History

Version	Compiled by	Date	Description
7	Dean Forster	6/7/2020	New Advena template with the content of Issue 6 of MedChip original format DoC. (ECO CN326)
7.1	Dean Forster	18/6/2024	Adjusted signature section to be more eSignature friendly. No other change.
8	Dean Forster	22/7/2025	Removed Mobile App