

## MIR DECLARATION

MIR s.r.l. Medical International Research manufacturer of medical devices hereby declares as follow:

The spirometers:

- Spirolab
- Spirobank II
- Spirodoc
- MiniSpir
- MiniSpir Light
- Spirotel
- Smart One
- Spirobank smart

Are in compliance with the Standard:

ISO 26782: 2009 "Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans".

Tests were performed using the waveform generator which is able to reproduce the curves defined in the Standard. The devices accuracy volume reading in the measurement range is lower than  $\pm$  3,0 % of reading or 0,05 l (whichever is greater) as defined in point 7.1 of the Standard.

Rome 30.06.2020

Sincerely

Paolo Boschetti Sacco

MIR Chairman