

DECLARATION OF CONFORMITY CE

(annex II excluding par.4)

MIR s.r.l. Medical International Research manufacturer of the following device:

Type Spirometer

Brandname MIR Medical International Research

Device name Smart One

Class

hereby declares that it COMPLIES with the Essential Requirements of directive 93/42/EEC concerning Medical Devices, and its amendments, and its transposition in the Member States.

This statement is made on the basis of the CE Certificate n. MED 9826 issued by Kiwa Cermet Italia s.p.a., Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Notified Body n. 0476.

This declaration is issued in compliance with Directive 93/42 and under the sole responsibility of the manufacturer.

Rome 01.01.2021

Paolo Sacco Boschetti The Chairman

Bretell