PULMEQ
PULMONOLOGY EQUIPMENT

EU DECLARATION OF CONFORMITY

PQ-04:22:Z

We: PULMEQ Sp. z o.o.
Ul. Mieszka I 66c
66-400 Gorzów Wielkopolski

declare, that the products with the CE marking and according to the list below, to which the declaration relates, comply with the requirements covered by the *93/42/EEC* directives, provided that they are used as intended.

Product class: *IIa, rule 5*
Sterile: *No*
Measuring function: *No*

Disposable spirometer filter:

Model:	*Description:*
PQFS-28	Spirometer filter, inner diameter about 28 mm
PQFS-30	Spirometer filter, inner diameter about 29 mm
PQFS-30S	Spirometer filter, inner diameter about 30 mm

The CE marking is located on the packaging.

The product is manufactured in accordance with the standards:

PN-EN 1041+A1:2013-12	PN-EN ISO 13485:2016
PN-EN ISO 14971:2012	PN-EN ISO 15223-1:2017-02
PN-EN ISO 10993-18:2020-11	PN-EN ISO 26782:2009
ISO 10993-1:2018	

Pulmeq sp. z o.o. applies a quality assurance system for production and final inspection in accordance with the requirements of Directive *93/42/EEC*. The Manufacturer's system also meets the requirements of ISO 13485:2016 in the following scope: *Production and sale of inactive medical devices for spirometry*.

The *TUV NORD Polska sp. z o.o.,* ul. Mickiewicza 29, 40-085 Katowice, took part in the conformity assessment.

Conformity confirmed by certificate number: TNP/MDD/0377/5150/2021

Documentation of the, above-mentioned, product is stored at the premises of the Manufacturer.

Valid from: *15/05/2022*

CE 2274

CEO
Jacek Baranowski