

EU DECLARATION OF CONFORMITY

PQ-04:21: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: *Ila, rule 5*
Sterile: *No*
Measuring function: *No*

Disposable spirometer mouthpiece:

Model:	Description:
PQUS-20	Spirometer mouthpiece, inner diameter about 20mm
PQUS-21	Spirometer mouthpiece, inner diameter about 21mm
PQUS-22	Spirometer mouthpiece, inner diameter about 22mm
PQUS-26	Spirometer mouthpiece, inner diameter about 26mm
PQUS-28	Spirometer mouthpiece, inner diameter about 28mm
PQUS-28P	Spirometer mouthpiece, inner diameter about 28mm
PQUS-30	Spirometer mouthpiece, inner diameter about 29mm
PQUS-30S	Spirometer mouthpiece, inner diameter about 29mm
PQUS-31	Spirometer mouthpiece, inner diameter about 30mm

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: **01/04/2020**



CEO
Jacek Baranowski
J. Baranowski