

CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

LifeFlow Sp. z o.o.
al. Kasztanowa 3A-5, PL / 53-125 Wrocław

applies a management system in line with the above standard for the following scope

Software for non-invasive measurement of Fractional Flow Reserve (FFR).

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1894/4950/2019**

Valid from **21-11-2019**

Audit Report No. PL4950/2019

Valid until **20-11-2022**



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 21-11-2019

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o.

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QMS