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

METRUM CRYOFLEX
Spółka z ograniczoną odpowiedzialnością Spółka Komandytowa
ul. Zielna 29, PL / 05-082 Blizne Łaszczyńskiego

with the location/site according to the annex

ul. Kolejowa 16A, PL / 05-092 Łomianki

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

Design, manufacture, sales and service of medical devices: cryosurgery, high energy medical lasers, local and general cryotherapy/cryostimulation, ozonotherapy, pressure massage/lymphatic drainage and distribution of medical devices.

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/1177/2075/2016**

Audit Report No. PL2075/2019-06

Valid from **09-08-2019**

Valid until **01-08-2022**

Initial certification: 29-07-2016

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

Katowice, 09-08-2019

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. ul. Mickiewicza 29 40-085 Katowice www.tuv-nord.pl

AC 090
QMS