DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **OOO NPF “Rehabilitation technologies”**

Address: 603136 Nizhniy Novgorod, General Ivliev st. 39,ap. 64, RUSSIA

2) Product(s) *(name, type or model/batch number, etc.)*:

- Biofeedback Treadmills of the Reaterra series
  Class 2a according to annex IIX, rule 9 of Regulation (EU) 2017/745

3) The product(s) described above is in conformity with:

Title	Document No.
1. Medical Device Regulation	1. (EU) 2017/745
2. Medical electrical equipment. Part 1-6. General requirements for basic safety and essential performance. Collateral standard. Usability	2. IEC 60601-1-6:2010
3. Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests	3. IEC 60601-1-2-2014
4. Medical devices. Quality management systems. Requirements for regulatory purposes	4. ISO 13485:2016
5. Medical devices. Software. Life cycle processes	5. IEC 62304-2013
6. Information technology. Software packages. Quality requirements and testing	6. ISO/IEC 12119-94
7. Information technology. Software product evaluation. Quality characteristics and guidelines for their use.	7. ISO/IEC 9126-93
8. Medical devices — Application of risk management to medical devices	8. ISO 14971

Emelianov Alexander , Director

Nizhniy Novgorod, RUSSIA; 2024-09-02 ----------

(Place & date of issue (yyyy-mm-dd)) *(name; function and signature o*