UE Declaration of Conformity

Manufacturer: **Rako Optyk Serwis Sp. z o.o.**
ul. Narutowicza 12, 70-240 Szczecin, Poland
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Ensures and declares on sole responsibility that the medical device: Spectacles frames

Basic UDI-DI: 5904753OPTFRAMEJS

Name of the Device: **SPECTACLES FRAMES :**
KENCHI, PASSION, N-JOY, MAGNETIC, PICOLLO

Complies with the applicable requirements of the Regulation of the European Parliament and of the Council (EU) 2017/745 of April 5, 2017 on medical devices, amendments to Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) No.1223/2009 and repealing Council Directive 90/385/EEC and 93/42/EEC.
It has been classified according to the rules in Annex VIII of the above mentioned Regulations as a Class I product according to Rule 1.

CE

List of standards used to demonstrate compliance:
ISO 12870:2018, EN ISO 14971:2019, EN ISO 13485:2016, EN ISO 10993-1:2020, PN-EN ISO 10993-18:2020-11, PN-EN ISO 20417:2021-10, EN 15223:1-2017-02, EN 62366-1:2015

CEO Andrzej Rakowski

Szczecin, August 8th, 2022