Warsaw, 16.09.2024.

**DECLARATION OF CONFORMITY**

|  |  |
| --- | --- |
| Manufacturer's name and address | **OROMED SZYMANEK Sp.k** ul. Ptasia 1060-319 Poznań |
| We declare under our sole responsibility that the Otoscope |
| Nazwa wyrobu  | Otoskop  |
| Model | Basic UDI-DI |
| ORO-OT 100 | 5904305746ORO-OT100JA |
| Class I medical device, rules 12SRN No.: PL-MF-000032079 | In accordance with Annex VIII to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| I declare with full and sole responsibility that the products specified above comply with the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amendments to Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and the following standards: |
| Quality Management System EN ISO 13485:2016Registration number: SX 1024101-1Valid until: 2026-10-26 |
| Signature: Anna BledziewskaPosition: Export ManagerDate: 16.09.2024 |

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V.1.0 z dnia 02.06.2023