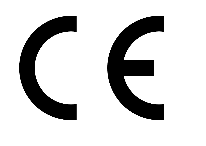
Warsaw, 16.09.2024.

**DECLARATION OF CONFORMITY**

|  |  |
| --- | --- |
| Manufacturer's name and address | **OROMED SZYMANEK Sp.k**  ul. Ptasia 10  60-319 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 12  SRN 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 13485:2016  Registration number: SX 1024101-1  Valid until: 2026-10-26 | |
| Signature: Anna Bledziewska  Position: Export Manager  Date: 16.09.2024 | |

****Obraz zawierający tekst, clipart

Opis wygenerowany automatycznie

V.1.0 z dnia 02.06.2023