# UE DECLARATION OF CONFORMITY

according to Medical Device Regulation of European Parliament
from April 5, 2017
**MDR 2017/745 Annex IV**

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer.

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| Product name | Stetoskop SPL |
| Type, model, version | Cardiology: SPL-CC; SPL-CD<br>Internal medicine: SPL-SC; SPL-SD; SPL-OA<br>Pediatrics: SPL-OP<br>Neonatal: SPL-OI<br>Anesthetics: SPL-U; SPL-E |
| Basic UDI-DI | 5906109631stetoskopSPLDM |

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| Manufacturer's name and address | Przedsiębiorstwo Produkcyjno-Handlowe<br>STETOSKOP.PL mgr inż. Radosław Filipowicz<br>Daniek 2, 99-420 Łyszkowice, Polska<br>www.stetoskop.pl |

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| Intendent purpose | A medical diagnostic tool used<br>for auscultation of a patient |
| Classification of the product according to MDR Annex VIII, Rule 1 | Medical Device Class I |

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| Quality Management System | Harmonized standards applied for medical devices<br>EN ISO 13485:2016<br>EN ISO 14971:2019<br>EN ISO 15223-1:2021 |

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| Warszawa, 2021-05-26 | STETOSKOP.PL<br>Przedsiębiorstwo Produkcyjno-Handlowe<br>mgr inż. Radosław Filipowicz<br>ul.Daniek 2, 99-420 Łyszkowice, Polska<br>NIP PI5271344406 ; Regon 017380794 |
| place and date of issue | mgr inż. Radosław Filipowicz - company owner |