

# EU DECLARATION OF CONFORMITY

according to Annex IV, Regulation (EU) 2017/745 of the European Parliament and of the Council

## 2014/03 (EN)

1. **Manufacturer:** **ARIES, a.s.**  
Žižkova 512, 543 01 Vrchlábí  
ID No.: 28824563 recorded in the Commercial Register by the Regional Court in Hradec Králové, Section B, Insert 3022  
Single registration number (SRN): CZ-MF-000047385
2. This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.
3. Basic UDI-DI code according to Annex VI, Part C: **85900722014032W**
4. **Product name:** **Avicenum PHLEBO 70 tights**  
**Trade name:** Avicenum PHLEBO 70 tights  
**Product variants:** **closed toe, small gusset, size S, M, L, XL**  
**closed toe, large gusset, size S+, M+, L+, XL+**  
**closed toe, extra large gusset, size M, L, XL**  
**Intended use:** The medical device intended for the compression therapy of venous conditions and swelling of the legs of various origin.
5. Class I medical device according to Annex VIII, Chapter III., Section 4.1. Rule 1, Regulation (EU) 2017/745 of the European Parliament and of the Council.
6. This medical device complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council. The product meets the basic requirements and is effective and safe for its purpose in normal use.  
The manufacturer has taken measures to ensure the conformity of all medical devices placed on the market with their technical documentation and with the general requirements for safety and performance according to Annex I, Regulation (EU) 2017/745 of the European Parliament and of the Council.  
The procedure according to Regulation (EU) 2017/745 of the European Parliament and of the Council was used in the prescribed manner to assess the basic properties of the product.
7. To prove the conformity, the following technical regulations, harmonised Czech technical standards or documentation or regulations were used:
  - a) EN ISO 13485:2016 Medical devices — Quality Management Systems — Requirements for Regulatory Purposes.
  - b) EN ISO 14971:2019 Medical devices — Application of Risk Management to Medical Devices.
  - c) EN ISO 15223-1:2016 Medical devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied.
8. The medical device is properly affixed with the “CE” marking of conformity in accordance with paragraphs 1, 2, 3 of Annex V, Regulation (EU) 2017/745 of the European Parliament and of the Council.
9. An authorised person did not participate in the conformity assessment.

<b>Declaration of Conformity No. EU 2014/03 (EN)</b> <b>Avicenum PHLEBO 70 tights</b>	REVISION 09 in Vrchlábí 20. 08. 2025	Page 1 / 1
Approved by: Ing. Ladislav Šulc Chairman of the Board		