EU DECLARATION OF CONFORMITY

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

2014/07 (EN)

1. **Manufacturer:** **ARIES, a.s.**
   512 33 Studenec u Horek 309
   ID No.: 28824563 recorded in the Commercial Register by the Regional Court in Hradec Králové, Section B, Insert 3022

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: **859007220140736**

4. Product name: **Avicenum PHLEBO 360 Calf-Length Stockings**

   Trade name: Avicenum PHLEBO 360 Calf-Length Stockings

   Product variants: **open toe, size S minus - XXL plus normal, S minus - XXL plus long**
   closed toe, size S minus - XXL plus normal, S minus - XXL plus long

   Intended use: This medical device is intended for compression therapy of circulatory disorders and various types of oedema in the leg.

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.
   d) RAL – GZ 387/1-2008

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.