Declaration of Conformity

Manufacturer:
LIPOELASTIC a.s.
Radlická 608/2
150 00 Prague 5
Czech Republic

Product:
Compression garments
Classification: Class I Medical Device

Standard Identification:
ČSN EN ISO 13485:2016 – Medical devices
ČSN EN ISO 3758:2012 – Textiles – Care labelling code using symbols
ČSN EN ISO 15223-1:2016 – Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
ČSN EN ISO 14971:2019 Medical devices – Application of risk management to medical devices
Regulation (EU) 2017/745 of the European Parliament and of the Council
Regulation (EU) No 1007/2011 of the European Parliament and of the Council

Declaration:

We, LIPOELASTIC a.s, as the manufacturer of Class I medical devices, hereby declare that our products are designed and manufactured in compliance with the European Union Medical Device Regulation (MDR 2017/745). This declaration confirms our commitment to adhering to all applicable legal requirements, harmonized standards, and norms necessary to ensure the safety and efficiency of our products.

Additionally, LIPOELASTIC® compression garments are awarded with the OEKO-TEX® STANDARD 100 certificate, 02.0.8039 Hohenstein, which guarantees the absence of harmful substancies and is therefore harmless for human health.

Our products undergo the following process:

- **Design and Development:** Each product is designed in accordance with user requirements and clinical needs in mind, utilizing the latest technologies and materials.
- **Manufacturing Processes:** All manufacturing processes are documented and regularly audited to ensure that products are produced under controlled conditions and meet the established standards stated above.
- **Quality Control:** We conduct regular inspections of our products to ensure their compliance with MDR requirements and other relevant standards.

- **Traceability:** We maintain full traceability of our products from manufacturing to the end user, enabling swift identification and resolution of any potential issues.

By this declaration, we confirm that our medical devices are safe and effective for their intended use and comply with all relevant legislative and regulatory requirements. We are committed to continuously improving our manufacturing processes and product quality to consistently provide high-quality compression garments to our customers.

Date of Issue:

Signature: Mgr. Petr Remeš

Digitálně podepsal Mgr. Petr Remeš
Datum: 2024.11.15 16:00:26 +01'00'

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