

EU DECLARATION OF CONFORMITY

**Zakład Elektromechaniczny „ERHEM”
Hończak i Wspólnicy Spółka Jawna
ul. Puszkina 6, 39-200 Dębica**

registered in the Eudamed medical device database under SRN number:

PL-MF-000004773

We declare under our sole and exclusive responsibility that our product:

ERH DAFO

Basic UDI-DI: 590748013ERHDAFOM9

as an ankle-foot orthosis, to which this declaration relates, is in conformity with 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.

We declare that the device belongs to **Class I** according to Rule 1 of Annex VIII to Regulation (EU) 2017/745.

Additionally, the product meets the requirements of:

- **PN-EN ISO 15223-1:2022-01** Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements,
- **PN-EN ISO 20417:2021-10** Medical devices - Information to be supplied by the manufacturer,
- **PN-EN ISO 14971:2020-05** Medical devices - Application of risk management to medical devices,
- **PN-EN ISO 10993-1:2021-06** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Dębica, dnia: 31.05.2022 r.

 **ERHEM** Sp. j.
Hończak i Wspólnicy
39-200 Dębica, Puszkina 6
tel. 14 6812 380, fax 14 6812 381
NIP 872-000-66-67, Regon 850233275

Owner
"ERHEM" - Sp. j.
signature
mgr inż. Józef Hończak

ERHEM sp.j.
39-200 DĘBICA ul. Puszkina 6, Tel.+48 14 681 23 80
www.erhem.pl poczta@erhem.pl #erhem_pl
KRS 0000100071, NIP 872 000 66 67, Regon 850233275, Nr BDO: 000017712
SWIFT: PKOPPLPW konto nr PL 91 1240 4807 1111 0000 5531 4295
EUR 51 1240 4807 1978 0010 7128 5846

