

DECLARATION OF CONFORMITY

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

registered in the Eudamed database for medical devices under the SRN number:

PL-MF-000004773

We declare with full and sole responsibility that our products listed in the appendix, to which this declaration relates, being class I products, comply with the Regulation of the European Parliament and of the Council (EU) 2017/745 of April 5, 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.

In addition, the device meets the requirements of:

PN-EN ISO 15223-1: 2017-02 Medical devices - Symbols for use on medical device labels, labelling and information provided with them - Part 1: General requirements,

PN-EN 1041+A1:2013-12 Information provided by the manufacturer of medical devices,
PN-EN ISO 14971:2011 Medical devices - risk management for medical devices,

PN-EN ISO 10993-1:2010 Biological evaluation of medical devices - Part 1: Assessment and testing in a risk management process

Dębica, date: 26.05.2021r.

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mgr inż. Józef Hończak
signature

ERHEM sp.j.

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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



28. **Elbow Orthosis (EO);** *Elbow Orthosis (EO) ERH 56/1 Arm and forearm brace for redressing the elbow joint*
29. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 34/2 15-degree abducting shoulder brace*
30. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 59/1 Arm, forearm and shoulder brace*
31. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 34 Shoulder vest brace*
32. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 59 Shoulder joint stabilizer*
33. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 34/1 Arm and shoulder brace*
34. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 54 2-piece sling brace*
35. **Shoulder Orthosis (SO);** *Shoulder Orthosis (SO) ERH 57 2-piece sling brace with support*
36. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/M Knee joint stabilizer*
37. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/R Knee joint stabilizer with open patella*
38. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/R/1 Stabilizing patella*
39. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/F Brace stabilizing patella*
40. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/F/U Knee joint stabilizer with diagonal stripes*
41. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/K/S Short knee joint brace - Sport*
42. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/K/Z Short/closed knee joint brace*
43. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/K/P Short/half-open knee joint brace*
44. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/K/O Short/open knee joint brace*
45. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/Z Closed knee joint brace*
46. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/P Half-open knee joint brace*
47. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 35/O Open knee joint brace*
48. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 52/Z Closed shin and thigh brace*
49. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 52/P Half-open shin and thigh brace*
50. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 52/O Open shin and thigh brace*
51. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 46 One-splint knee joint brace*
52. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 46/1 One-splint knee joint brace*
53. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 46/2 One-splint brace stabilizing knee joint*
54. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 58 Splint and strap knee joint brace*
55. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 43 Open modular brace*
56. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 43/ Open modular brace with a cover*
57. **Knee Orthosis (KO);** *Knee Orthosis (KO) ERH 45 Open strap brace*
58. **Foot and shin orthosis;** *Foot and shin orthosis ERH 49 - Ankle joint brace - stabilizer*
59. **Foot and shin orthosis;** *Foot and shin orthosis ERH 49/2- Ankle joint brace*
60. **Foot and shin orthosis;** *Foot and shin orthosis ERH 49/3- Shin brace with a sandal*
61. **Foot and shin orthosis;** *Foot and shin orthosis ERH 49/5 Strap immobilizing and correcting foot and ankle joint*
62. **Foot and shin orthosis;** *Foot and shin orthosis ERH 71, Shin brace with a sandal*
63. **Strap immobilizing foot and ankle joint - Sport;** *ERH 49/1*
64. **Hip orthosis;** *Hip orthosis ERH 66 High hip brace with a splint*
65. **Hip orthosis;** *Hip orthosis ERH 66 Brace for the treatment of hip dysplasia*

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