

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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Owner
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signature

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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



Appendix to the above declaration:

1. **Torso brace**¹; *Torso brace ERH 53 Upright position (supporting) device of "eight" type*²
2. **Torso brace**; *Torso brace ERH 53 /1 Elastic upright position (supporting) device with reinforcement*
3. **Torso brace**; *Torso brace ERH 60 Elastic upright position (supporting) device with reinforcement*
4. **Torso brace**; *Torso brace ERH 36 Low sacral / lumbar belt*
5. **Torso brace**; *Torso brace ERH 37 Sacral / lumbar belt*
6. **Torso brace**; *Torso brace ERH 37/1 High sacral / lumbar belt*
7. **Torso brace**; *Torso brace ERH 61 Lumbar Support Belt*
8. **Torso brace**; *Torso brace ERH 62 Sacral / lumbar brace*
9. **Torso brace**; *Torso brace ERH 48 High semi-rigid brace*
10. **Torso brace**; *Torso brace ERH 48/1 High semi-rigid brace with underarm support*
11. **Torso brace**; *Torso brace ERH 48/2 High half-torso semi-rigid brace with underarm support*
12. **Torso brace**; *Torso brace ERH 48/3 for children (TLSO)*
13. **Torso brace**; *Torso brace ERH 69 High semi-rigid brace with underarm support for children*
14. **Back brace**; *Back brace ERH 65 cervical-thoracic brace*
15. **Back brace**; *Back brace ERH 51 3-point back brace by Bahler-Voigt*
16. **Back brace**; *Back brace ERH 63 the Jewett brace*
17. **Back brace**; *Back brace ERH 64 cervical-thoracic-lumbar-sacral brace*
18. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 38/2 Soft wrist stabilizer*
19. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 50 Universal wrist stabilizer*
20. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 38 Wrist stabilizer*
21. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 38/1 Thumb and wrist stabilizer*
22. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 47 Hand and forearm splint*
23. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 47/1 Hand and forearm splint with abducted thumb*
24. **Wrist-Hand Orthosis (WHO)**; *Wrist-Hand Orthosis (WHO) ERH 47/1 Wrist splint with abducted thumb*
25. **Elbow Orthosis (EO)**; *Elbow Orthosis (EO) ERH 42 Elbow brace*
26. **Elbow Orthosis (EO)**; *Elbow Orthosis (EO) ERH 42/1 Splint and strap arm and forearm brace*
27. **Elbow Orthosis (EO)**; *Elbow Orthosis (EO) ERH 56 Arm and forearm brace*

¹ Bold text denotes the trade name that is consistent with the trade name of the product contained in the application to URWM.

² Italics denotes the product model complies with the product model included in the application to URWM.

ERHEM sp.j.

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