

## DECLARATION OF CONFORMITY

No. 232/2020

Manufacturer:

**FORMED PRO Sp. z o.o.**  
ul. Ceramiczna 2; 34-325 Łodygowice  
tel./fax 0048 33 863 18 00  
email: [formed-pro@formed-pro.pl](mailto:formed-pro@formed-pro.pl)  
[www.formed-pro.pl](http://www.formed-pro.pl)

We declare that:

**Medical device:** HIRO – treatment table

**Commercial name:** HIRO

**Type:** HIRO - Variants are specified in the technical documentation of the product

**Class:** Class I by rule 1 according to annex IX Medical Directive 93/42/EEC

**This product carries the CE Mark and it is medical device according to Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements set out in Annex I of this Directive.**

**Procedure of assessing conformity:** Annex VII of Medical Devices Directive 93/42/EEC

Product meets the requirements of harmonized standards with Medical Devices Directive 93/42/EEC:

**PN-EN 60601-1:2011, PN-EN ISO 14971:2012, PN-EN 60601-2-46:2011, PN-EN ISO 19054:2006, PN-EN 1041:2010, PN-EN ISO 15223-1:2017-02, PN-EN 62366:2008.**

Łodygowice, 16.04.2020 r.



Stamp

**FORMED PRO Sp. z o.o.**  
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Signature

*mgr inż. Tomasz Kania*  
**Prezes Zarządu**  
*mgr inż. Tomasz Kania*

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