EC DECLARATION OF CONFORMITY

released according to §13, item 2 of the Act No. 22/1997 Coll. about products technical requirements as amended and according to the Government Regulation No. 54/2015 Coll. that defines technical parameters for medical devices as amended, (Hereinafter referred to as Medical device) according to Law No. 268/2014 Coll. about medical devices and amending Law no. 634/2004 Coll., on administrative fees amendment of some related legislation, as amended.

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hereby confirms

that for the medical device: **Mechanical adjustable bed**

type: **PLH-N70(80,85,90)-T; PLH-U70(80,85,90)-T; PLH-P70(80,85,90)-T; PLH-L70(80,85,90)-T; PLH-S70(80,85,90)-T; PLH-Z70(80,85,90)-T; PLH-K70(80,85,90)-T; PLH-E70(80,85,90)-T; PLL-N70(80,85,90)-T; PLL-U70(80,85,90)-T; PLL-P70(80,85,90)-T; PLL-L70(80,85,90)-T; PLL-S70(80,85,90)-T; PLL-Z70(80,85,90)-T; PLL-K70(80,85,90)-T; PLL-E70(80,85,90)-T; PLB-N70(80,85,90)-T; PLB-U70(80,85,90)-T; PLB-P70(80,85,90)-T; PLB-L70(80,85,90)-T; PLB-S70(80,85,90)-T; PLB-Z70(80,85,90)-T; PLB-K70(80,85,90)-T, PLB-E70(80,85,90)-T and applicable accessories**

was made the assessment of the conformity with the requirements for product safety according the legislation and the technical regulations, the procedure referred to in Government Regulation relating to the medical devices and

declares

1. that the above mentioned medical devices complies with all requirements stated in the Government Regulation No. 54/2015 Coll., as amended, that defines technical parameters for medical devices (according to European council directive 93/42/EEC)
2. that this medical device used with accordance to the user manual is safe, effective and suitable for medical care,
3. that this medical device is designed for treatment support, mitigation and compensation of injury or disability of the patient under medical supervision,
4. that this medical device is suitable for indoor use and it is classified into class I - non-sterile, without measuring function, according to rule 1 attachement No. 9 of Government Regulation No. 54/2015 Coll. (Medical devices directive 93/42/EEC), as amended, and that Conformity was assessed by the procedure attachement No. 7,
5. that those measures have been taken to ensure the conformity of all these medical devices introduced to the market with technical documentation and technical requirements,
6. that the products comply with the following standards: ČSN EN 60601-2-52 + Cor.1 + A1:2015, ČSN EN ISO 14971:2012, ČSN EN 1041+A1:2014, ČSN EN ISO 15223-1:2012,
7. that technical documentation is stored in the producer company headquarters,
8. that date of first CE marking of above mentioned products was 2.2.2002.

In Česká Skalice, 15.4.2016

company stamp

Zdeněk Jakubský
(legal representative)

We are authorized to use the above shown protected marks