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## ES - declaration of compliance no. S-001 Version 01/2013

In accordance with Directive 93/42/EEC on medical devices and Appendix VII

The manufacturer: HAM, the production of SpinaliS chairs, LLC  
Company's Registered Office: Gerbičeva ulica 102, 1000 Ljubljana, Slovenia  
Location of the production: Gerbičeva ulica 102, 1000 Ljubljana, Slovenia

With all the responsibility we hereby declare, that the below listed medical devices Class I  
(Appendix IX, Rule 1) – Therapeutic chairs SpinaliS of types:

<b>Ergonomic</b>	<b>Spider</b>
<b>Hacker</b>	<b>Apollo</b>
<b>Navigator</b>	<b>Basic</b>
<b>Pilot</b>	<b>Dent</b>
<b>Smart</b>	<b>Stylist</b>
<b>Rodeo</b>	

which are the subjects of this statement, comply with the requirements of the following regulations:

### Directive 93/42/EEC on medical devices

and the requirements of the following harmonized standards:

ISO 14971:2012	Medical devices. Application of risk management to medical devices	Published	31-jul-2012
ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	Published	01-apr-2012

To compile the technical files is to be in charge: Tomaž Ham, the responsible person of the company.  
The documentation shall be kept at the registered seat of the company.

Place and date of issue:

Ljubljana, Slovenia,  
15.10.2013



Signature of person  
responsible:  
Tomaž Ham,  
direktor

#### Warning:

The declaration of conformity loses its validity in cases of the intervention of unauthorized persons into the product, with a view to modification or service, failure to observe the instructions, which are included in the accompanying manual, in the event of improper use and maintenance of the product, etc. This statement applies solely to the product in the same condition in which it had been placed on the market, and excludes components which are added or operations carried out subsequently by the final user.