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EU declaration of conformity no. S-002

Version 09/2021

In accordance with Regulation (EU) 2017/745 on medical devices and Annex IV

The manufacturer:	HAM, the production of SpinaliS chairs, LLC
SRN no.:	SI-MF-000003203
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 – Therapeutic chairs for active sitting SpinaliS of types:

**Ergonomic
Hacker
Navigator
Pilot
Smart
Rodeo**

**Spider
Apollo
Basic
Dent
Stylist
Explorer**

The Basic UDI-DI: 383006315SPINALISMD7S

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

Regulation (EU) 2017/745 on medical devices

and the requirements of the following harmonized standards:

SIST EN ISO 14971:2020	Medical devices. Application of risk management to medical devices (ISO 14971:2019)	Published 01-May-2020
SIST EN ISO 13485:2018	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (ISO 13485:2016) – AC:2018	Published 01-May-2018

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, 22.9.2021

Signature of person responsible:

Tomaž Ham,
Director

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.