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EU Declaration of Conformity

COMPANY ZAPOVIT SUBSIDIARY

Manufacturer:

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Product Category:

Medical furniture - Tripods for long-term infusions

Models:

Tripod for long-term infusions ShDV-5

Tripod for long-term infusions ShDV-5n

Basic UDI-DI:

482027905MF-T-ShDV2B

Classification:

Class I, according to **Regulation (EU) 2017/745 (Medical Device Regulation - MDR)**, specifically under Rule 1 of Annex VIII.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards.

DIRECTIVES

General Applicable Directive:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices (Regulation (EU) 2017/745 on medical devices).

ISO 15223-1:2021

ISO 20417:2021

EN ISO 13485:2016

EN ISO 14971:2019

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(Place & date of issue (dd-mm-yyyy))

Olga Potyraiilo, Director

(name; function and signature of manufacturer)

