

# EC CONFORMITY DECLARATION

Date of issue: 20.08.2018

## **Conformity declaration issued by:**

Commercial name	SINOMED s.r.o.
Registered address	Štěchovická 2266/2, 100 00 Praha 10
Reg. No.	275 87 657
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## **As the authorized representative in EU**

### **Producer**

GUANGDONG KAIYANG MEDICAL TECHNOLOGY CO., LTD.  
Address: Yangfeng Industrial Area, Dali, Nanhai District, Foshan, Guangdong, China, Post code 528231  
Tel: 0086-757-85502506, Fax: 0086- 757-85502630

### **Product:**

Crutches

### **Classification of the product as the medical device:** Class I

### **Declaration:**

I declare that the said product is safe under the conditions of common use in compliance with the instruction and that measures have been taken to ensure the conformity of all the products brought to market with technical documentation and basic requirements of directives related thereto.

### **Fulfilled technical requirements:**


This product's characteristics comply with the technical parameters related to it and stated in statutory order No. 336/2004 which stipulates the technical parameters for healthcare products.

### **Means of assessing conformity**

Conformity was assessed by the procedure stated MDD 93/42/EEC.

### **Used norms**

The said product fulfills the requirements of these harmonized technical norms which were used for assessing of conformity: EN 12182:1999, EN 1985:1998, EN ISO 14971:2000, EN 1041:1998

  
Ing. Martin Těšitel  
director



Attachment to EC Conformity Declaration:

- EC Conformity declaration is relevant to the following crutches:

KY923L,  
KY937L,  
KY933L,  
KY935L(M),  
KY935L(L),  
KY935L(S),  
KY925L(L),  
KY925L(M),  
KY925L(S),  
KY935(S),  
KY935(M),  
KY935(L)

Prague 20.08.2018

