

## ES ATITIKTIES DEKLARACIJA

2021 m. lapkričio 8 d., Kaunas

Nr. 01/21

**Gamintojas:** UAB „Helfis“, įm.k. 305047398,

Adresas: Sodo g. 7-6, Jaunakaimio k.,  
58331 Kėdainių r., Lietuva.

### Informacija apie medicinos priemonę

Bendriniis pavadinimas: turniketas.

Paskirtis: stipriam (masyviam) kraujavimui galūnėse (rankose, kojose) stabdyti.

Nr.	Modelis	Bazinis UDI-DI
1.	LTQ 1.0	477905359LTQ1.0NW

**Gamintojas užtikrina jog medicinos priemonė, kuriai taikoma ši ES atitikties deklaracija, naudojama tinkamai yra saugi bei atitinka:**

2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamentą (ES) 2017/745 dėl medicinos priemonių, kuriuo iš dalies keičiama Direktyva 2001/83/EB, Reglamentas (EB) Nr. 178/2002 ir Reglamentas (EB) Nr. 1223/2009, ir kuriuo panaikinamos Tarybos direktyvos 90/385/EEB ir 93/42/EEB.


MEDICINOS PRIEMONĖS KLASIFIKACIJA: 1 klasė, pagal (ES) 2017/745.

RIZIKOS KLASIFIKAVIMO TAISYKLĖ: 1 taisyklė, VIII priedas, pagal (ES) 2017/745.

ATITIKTIS DEKLARUOJAMA REMIANTIS: II, III priedai, pagal (ES) 2017/745.

Ši ES atitikties deklaracija išduota tik gamintojo atsakomybe.

UAB „Helfis“  
Direktorius



Mindaugas Sinickas

UAB „Helfis“, įm.k. 305047398, Sodo g. 7-6 Jaunakaimio k., 58331 Kėdainių r., Lietuva.  
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## EU DECLARATION OF CONFORMITY

8 November 2021, Kaunas

No. 01/21

**Manufacturer:** Helfis, UAB (Private Limited Liability Company), company ID 305047398,  
**Address:** Sodo g. 7-6, Jaunakaimio k.,  
58331 Kėdainių r., Lithuania.

### Information about the medical device

Common name: turnstile.

Purpose: to stop strong (massive) bleeding in the limbs (arms, legs).

No.	Model	Basic UDI-DI
1.	LTQ 1.0	477905359LTQ1.0NW

**The manufacturer ensures that the medical device covered by this EU Declaration of Conformity is safe when used properly and conforms:**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

CLASSIFICATION OF THE MEDICAL DEVICE: Class 1, according to (EU) 2017/745.

RISK CLASSIFICATION RULE: Rule 1, Annex VIII, in accordance with (EU) 2017/745.


CONFORMITY DECLARED ON THE BASIS OF: Annexes II, III, according to (EU) 2017/745.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Helfis, UAB

Director



 Mindaugas Sinickas

/logo/  
**HELFIS****EU DECLARATION OF CONFORMITY**

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Helfis, UAB

Director /stamp: „Republic of Lithuania · Kedainiai Region ·  
 Helfis, UAB (Private Limited Liability Company)“/ /signed/ Mindaugas Sinickas

Helfis, UAB (Private Limited Liability Company), company ID 305047398, Sodo g. 7-6  
 Jaunakaimio k., 58331 Kėdainių r., Lithuania. [www.helfis.lt](http://www.helfis.lt) [info@helfis.lt](mailto:info@helfis.lt)

12 July 2022

Translation is correct.

Translated by: Translator Asta Lipniuvienė

I, Asta Lipniuvienė, acting on behalf of the Personal Enterprise *Astos Lipniuvienės įmonė*, legal entity code 261636470,  
 registered office: Dvaro str. 11, Kedainiai, assume full responsibility for correctness of the above translation from  
 Lithuanian into English.

Stamp, signature



*Asta Lipniuvienė* 

/stamp: "REPUBLIC OF LITHUANIA · KEDAINIAI · Astos Lipniuvienės įmonė (Asta Lipniuvienė Enterprise)"/