

EU DECLARATION OF CONFORMITY AS PER ANNEX IV OF THE REGULATION (EU) MDR 2017/745

№ 1
version 2

Manufacturer:	<i>Full name:</i> LIMITED LIABILITY COMPANY «SICH UKRAINE» <i>Abbreviated name of the Manufacturer:</i> «SICH UKRAINE» LLC 4 Lomonosova str., off. 46, Kyiv, 03040, Ukraine; registration number: 39540411; +38 (097) 609-33-79; sichtourniqet@gmail.com
EU Authorized Representative:	VORWARTS PHARMA SP. Z O.O. Company adress: ul.Zurawia 43/304, 00-680, Warsaw, Poland +48 732 639 545 / vp.marketing.pl@gmail.com
The name of the medical product:	Tourniquet to stop the bleeding «SICH-Tourniquet»
Intended Purpose:	This is a single-use mechanical device for temporarily stopping arterial and venous bleeding of the upper and lower extremities, intended for use in medical facilities, rescue services, for individual use in the field, at home and in transport, in areas of tactical emergency medical assistance
Risk Class per Annex VIII:	Class I (non-invasive, non-sterile, non-measuring, non-reusable) as per Rule 1
The declaration object described above meets the requirements:	The applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 to medical devices (version 20/03/2023)
Conformity assessment procedure:	In accordance with Clause 7 of Article 52 of the Regulation (EU) 2017/745 of 5 April 2017 (version 20/03/2023) to medical devices, «SICH UKRAINE» LLC utilizes the technical documentation in accordance with the requirements of Annex II and Annex III for class I medical devices and issues a Declaration of Conformity (self-certification).
Validity period of the declaration:	from 2024-11-12 without limitation of validity period
Basic UDI-DI	4820214250015Q

This declaration of conformity is issued under the sole responsibility of the manufacturer «SICH UKRAINE» LLC.

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

Director «SICH UKRAINE» LLC

Oleksandr HADOMSKYI

Kyiv / «12» November 2024 y.
(place of issue and date of issue)

