




EU DECLARATION OF CONFORMITY

according to Regulation (EU) 2017/745 issued under the sole responsibility of the manufacturer

Manufacturer	STS Medical Group AD Industrial Area Sokolovetz 2800 Sandanski Bulgaria		
Single Registration Number (SRN):	BG-MF-000041809		
This Declaration of Conformity is valid for following medical devices:	SECUDRAPE- Limb transport bags The reference numbers of devices are listed in Annex1		
Classification of Medical device according to Regulation (EU) 2017/745 Annex VIII and intended use	Intended use: Limb transport bags are systems of inner and outer bag suitable to hold and carry amputated limbs. Classification: Class I, rule 1		
CE Marking:	CE0425		
Notified Body:	ICIM S.P.A. Piazza Don Enrico Mapelli, 75 20099 - Sesto San Giovanni (MI), Italy		
EU Certificate:	EU Certificate number: 0425-MDR-030145-00 EU Certificate issue date: 01-08-2025 For devices under certification: Annex XI, part A, Section 10		
Manufacturer statement	We, the legal manufacturer, hereby declare that the medical devices listed in Annex 1: <ul style="list-style-type: none">• Comply with the provisions of Regulation (EU) 2017/745• Are subject to a certified Quality Management System under supervision by a certification entity. All supporting documentation is retained at the premises of the manufacturer.		
Declaration of Conformity	Revision	Place and Date	Approval by
DOC-MDR-TD-04-04-EN	01	Sandanski, Bulgaria 19.09.2025	 Anita Chacheva STS Medical Group AD QM Manager and PRRC

ANNEX I**This Declaration of Conformity is valid for the following medical devices:**

REF	Product name	Basic UDI-DI
CPC0001	LIMB TRANSPORT BAG SIZE M	380023TD04LTPEST9A
CPC0002	LIMB TRANSPORT BAG SIZE L	380023TD04LTPEST9A
CPC0003	LIMB TRANSPORT BAG SIZE XL	380023TD04LTPEST9A
CPC0072	FINGER REIMPLANTATION BAG 20X20CM	380023TD04LTPEST9A
CPC0073	ARM REIMPLANTATION BAG 70X25CM	380023TD04LTPEST9A
CPC0073-01	ARM REIMPLANTATION BAG 70X25CM	380023TD04LTPEST9A
CPC0074	LEG REIMPLANTATION BAG 110X40 CM	380023TD04LTPEST9A
CPC0074-01	LEG REIMPLANTATION BAG 110X40 CM	380023TD04LTPEST9A
CPC0071	HAND REIMPLANTATION BAG 30X25 CM	380023TD04LTPEST9A
CPC0071-01	HAND2 REIMPLANTATION BAG 30X25 CM	380023TD04LTPEST9A
CPC0075	HAND REPLANTATION BAG 30X25CM	380023TD04LTPEST9A
D04XXXX*	Limb transport bags, sterile	380023TD04LTPEST9A

*XXXX= consecutive number starting from 0001