SURGIKARE
DECLARATION OF CONFORMITY

Document#	DOC-01/01-02
REV-00	26.05.2021
Rev-01	18-10-2022 Revision in the Risk standard
ReV-02	1-8-2025 Revision in format

We declare, under our sole responsibility, that the products that Surgikare is supplying to the Medika are in Conformity With the Following Standard(s) or Other Normative Document(s) and European Council Directive 93/42/EEC as amended by Directive 2007/47/EC. We confirm that no significant changes in the design or intended use have been made since 26.05.2021.

Manufacturer's Name & Business Address:	**Surgikare** Toor Abad Daska Road, Sialkot-51310, Pakistan.	
EC REP	**Obelis S.A** Bd. General Wahis, 53 1030 Brussels, Belgium Tel: +32 2 732 5954 Fax: +3227326003 Email: sales@obelis.net	
Product Details:	**SKG-30-186 Umbilical Cord Cutting Clamp**	
MDD Annex:	V	
Classification:	Class 11a	
Classification Rule:	6	
Certificate #:	PK09/78031 (ISO 13485:2016) PK19/818842593 (Directive 93/42/EEC)	
Notified Body Number:	1639	
Notified Body Address:	SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp, Belgium	
Standards Applied:	**EN ISO 14971:2019**	Medical devices - Application of risk management to medical devices
	ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	EN 1041:2008	Information supplied by the manufacturer of medical devices
	ISO 7153-1:2016	Surgical instruments - Materials - Part 1: Metals
	IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
	ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
	ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
	ISO 11737-2:2019	Sterilization of medical devices, Microbiological methods, Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
	ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

Authorized Signatory:

SURGIKARE TOOR ABAD DASKA ROAD SIALKOT PAKISTAN

Sabir Ghumman (QA Manager)

01-08-2025
Date