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.

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-30-767 bone curette D/E 16 cm**	
MDD Annex:	V	
Classification:	Class IIa	
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 14971:2012**	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