To whom may it concern,

We, **T-BİYOTEKNOLOJİ LABORATUVAR ESTETİK MEDİKAL KOZMETİK SAN. TİC. LTD. ŞTİ.,** registered adress at **Tahtalı Mh. Değirmen Yolu(460) Sk. No:10 NİLÜFER BURSA** is the owner of PRPPROF brand.

PRPPOF PRP KIT product technical specifications as identifed below,

Manufacturer Information	
Legal Manufacturer:	T-BIYOTEKNOLOJI LABORATUVAR ESTETIK MEDIKAL KOZMETIK SAN. VE TIC. LTD. STI.
Legal Manufacturer & Production & Sterilization Facility Address:	Tahtalı Mah. Değirmen Yolu (460) Sk. No:10 Nilüfer / Bursa TURKEY
Manufacturer ID No (SRN)	TR-MF-000016403
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A General Description

PRP TUBES is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is prepared prior to application to a local area of soft tissue or hard tissue (including bone) site as deemed necessary by the clinical use requirements. And its intended use is for the application of PRP in order to achieve the stimulation of soft tissue and hard tissue (including bone) and acceleration of soft tissue and hard tissue (including bone) healing.

The Platelet Enhancement process is based on molecular weight of cell separation due to a centrifugal force. As proved with publications on analytical and clinical peer reviewed journals, concentrated platelet layers, referred to Platelet Rich Plasma, help soft tissue and hard tissue (including bone) healing. PRP is most commonly used in the treatment of Orthopedic Joint Damage and Alopecia Areata.

The procedure uses blood collected by routine phlebotomy. PRP TUBES contain sodium citrate which prevents coagulation of whole blood outside the human body. Platelet-rich plasma tubes containing sodium citrate, is thought to have the capacity to stimulate and accelerate the healing of soft tissue and hard tissue (including bone) regeneration.

Effective PRP preparation is essential to obtaining high quality platelet. Platelet damage that occurs during preparation step can cause growth factors to be not secreted and result in an unsuccessful treatment. Whole blood centrifugation is a basic method to produce PRP. In whole blood centrifugation, a bench top centrifuge is used as fast gravitational force separates the components of the blood based on molecular weight of the cells. The separation occurs during centrifugation when the denser blood components move due to a gravity force.

The generally known PRP layer is volumetrically above the Red Blood Cells Layer. PRP layer is collected into either a separate tube or a syringe, with RBC layer and/or PPP (Platelet Poor Plasma) layer left in PRP TUBES. The result is a convenient aseptic system, collection of whole blood, processing to

obtain the PRP layer and the concentration of Platelet Rich Plasma. PRP TUBES reduces the risk of blood borne contaminations.

PRODUCT FEATURES		
Device Presentation	Blister packaging containing 2 tubes or 1 tube, electronic IFU	
Device Packaging Material	Blister & Tyvek 1073B	
Shelf Life	24 Months	
Single Use or Reusable	Single Use	
Tube Volume	10 ml	
Centrifugation Force	See. TF.03.IFU	
Centrifugation Time		
Sterile	Sterile	
Sterilization Method	Radiation	
Pyrogen Free	Product is pyrogen free	
BPA Free	Not made with BPA	
DEHP Free	Not made with DEHP	
Latex Statement	Not made with natural rubber latex	

RULE	APPLICABLE DEFINITION	CLASS
93/42/EEC Annex IX Rule 3	All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb,	IIb

PART OF THE MEDICAL DEVICE		MATERIAL / RAW MATERIAL	BODY CONTACT
PRP TUBE	Tube	Polyethylene terephthalate (PET)	Indirect Blood Path
	Cap	Polyethylene (HDPE) (DOW)	No Contact
		Polyethylene (LDPE)	No Contact
	Rubber Stopper	Butyl Rubber	No Contact
	Label	UPM Raflatac self-adhesive labelstock	No Contact
ANTICOAGULANT		Sodium Citrate Dihydrate Solution (alternative)	Indirect Blood Path
		Distiled Water	Indirect Blood Path

PART OF THE MEDICAL DEVICE	MATERIAL / RAW MATERIAL		BODY CONTACT
	9NC-1000	Sodium Citrate Dihydrate	Indirect Blood Path
		Citric Acid	Indirect Blood Path
TYVEK	Tyvek 1073B		No Contact
BLISTER	Polyethylene (PET)		No Contact

STANDARD NO.	STANDARD TITLE
HARMONIZED STANDARDS	
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993- 18:2020	Biological evaluation of medical devices: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23: 2021	Biological evaluation of medical devices - Part 23: Tests for irritation
NON-HARMONIZED STANDARDS	
EN ISO 10993-2: 2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN 62366-1:2020	Medical devices — Application of usability engineering to medical devices
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2010	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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
EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release
EN ISO 11137-1:2015	Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods
EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
EN 556-1:2001/AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Part 1. Requirements for terminally sterilized medical devices
ISO 6710:2017	Single-use containers for human venous blood specimen collection
ASTM F1980:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
ASTM F1929:2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F88 F88M:2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1886:2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
BS EN 868-5:2018	Packaging for terminally sterilized medical devices Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods
GUIDANCE DOC.	**GUIDANCE DOCUMENT TITLE**
MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev.8	Guidelines on a Medical Device Vigilance System
MEDDEV 2.12/2 Rev.2	Guidelines on Medical Devices Post Market Clinical Follow-Up Studies
MEDDEV 2.4-1 Rev.9	Guidance document - Classification of Medical Devices
MDCG 2018-1 Rev.4	Guidance on BASIC UDI-DI and changes to UDI-DI
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies
MDCG 2020-3	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2020-5	Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2021-19	Guidance note integration of the UDI within an organisation’s quality management system
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745