EC Declaration of Conformity

issued in accordance with EC directive 93/42/EEC relating to Medical Devices

Manufacturer: T-BIYOTEKNOLOJI LABORATUVAR ESTETIK MEDIKAL KOZMETIK SAN. VE TIC. LTD. STI.

Address: Tahtalı Mah. Değirmen Yolu (460) Sk. No:10 Nilüfer / Bursa TURKEY

Device Name: PRP TUBES

Brands:

T-LAB PRP TUBES (T1002), PRPHD PRP TUBES(HD1002), NEXT PRP TUBES (N1002), NATURALHAIR PRP TUBES (NHT1002), CLINICEXPERTLABS PRP TUBES (CEL1002), CELLHD PRP TUBES (C1002), PRPPROF TUBES (PP1002), PRPEXPERT TUBES (PE1002), XFACTOR PRP TUBES(X1002), YAVOPRP TUBES (Y1002), MEDEX PRP TUBES (M1002), INNMEDIS PRP TUBES (IN1002), ELITIN PRP TUBES (E 1002), QUANTIX PRP TUBES (Q1002), AUTOSOMA PRP TUBES (A1002), ABALASE PRP TUBES (AB1002), OPUSS PRP TUBES (OP 1002), PROXELL PRP TUBES (PX 1002), PROGENİS PRP TUBES (PG 1002), GROWEX PRP TUBES (GR 1002), ARTHROPEX PRP TUBES (AR 1002), CUREVİTAL PRP TUBES (CU 1002), VİVERA PRP TUBES (VI 1002), RENEWEX PRP TUBES (RN 1002), REJUVERA PRP TUBES (RJ 1002), JOUVENCE PRP TUBES (JO 1002), PLASMOO PRP TUBES (PLO1002), DIVES MED PRP TUBES (DVM1002), MAXXI PRP TUBES (MX1002), ATR PRP TUBES (ATR1002), PRPVET PRP TUBES (VT1002), GYNO-SHOT PRP TUBES (GSH1002), UNICELL PRP TUBES (UC 1002), PRIMA PRP TUBES (PR 1002), MIKADO PRP TUBES (MK 1002), TAILORED PRP TUBES (TL 1002), REMEDEX PRP TUBES (RM 1002)

T-LAB PRP TUBES (T1003), PRPHD PRP TUBES(HD1003), NEXT PRP TUBES (N1003), NATURALHAIR PRP TUBES (NHT1003), CLINICEXPERTLABS PRP TUBES (CEL1003), CELLHD PRP TUBES (C1003), PRPPROF TUBES (PP1003), PRPEXPERT TUBES (PE1003), XFACTOR PRP TUBES(X1003), YAVOPRP TUBES (Y1003), MEDEX PRP TUBES (M1003), INNMEDIS PRP TUBES (IN1003), ELITIN PRP TUBES (E1003), QUANTIX PRP TUBES (Q1003), AUTOSOMA PRP TUBES (A1003), ABALASE PRP TUBES (AB1003), OPUSS PRP TUBES (OP 1003), PROXELL PRP TUBES (PX 1003), PROGENİS PRP TUBES (PG 1003), GROWEX PRP TUBES (GR 1003), ARTHROPEX PRP TUBES (AR 1003), CUREVİTAL PRP TUBES (CU 1003), VİVERA PRP TUBES (VI 1003), RENEWEX PRP TUBES (RN 1003), REJUVERA PRP TUBES (RJ 1003), JOUVENCE PRP TUBES (JO 1003), PLASMOO PRP TUBES (PLO1003), DIVES MED PRP TUBES (DVM 1003), MAXXI PRP TUBES (MX1003), ATR PRP TUBES (ATR1003), PRPVET PRP TUBES (VT1003), GYNO-SHOT PRP TUBES (GSH1003), UNICELL PRP TUBES (UC 1003), PRIMA PRP TUBES (PR 1003), MIKADO PRP TUBES (MK 1003), TAILORED PRP TUBES (TL 1003), REMEDEX PRP TUBES (RM 1003)

T-LAB PRP TUBES (T1004), PRPHD PRP TUBES(HD1004), NEXT PRP TUBES (N1004), NATURALHAIR PRP TUBES (NHT1004), CLINICEXPERTLABS PRP TUBES (CEL1004), CELLHD PRP TUBES (C1004), PRPPROF TUBES (PP1004), PRPEXPERT TUBES (PE1004), XFACTOR PRP TUBES(X1004), YAVOPRP TUBES (Y1004), MEDEX PRP TUBES (M1004), INNMEDIS PRP TUBES (IN1004), ELITIN PRP TUBES (E1004), QUANTIX PRP TUBES (Q1004), AUTOSOMA PRP TUBES (A1004), ABALASE PRP TUBES (AB1004), OPUSS PRP TUBES (OP 1004), PROXELL PRP TUBES (PX 1004), PROGENİS PRP TUBES (PG 1004), GROWEX PRP TUBES (GR 1004), ARTHROPEX PRP TUBES (AR 1004), CUREVİTAL PRP TUBES (CU 1004), VİVERA PRP TUBES (VI 1004), RENEWEX PRP TUBES (RN 1004), REJUVERA PRP TUBES (RJ 1004), JOUVENCE PRP TUBES (JO 1004), PLASMOO PRP TUBES (PLO1004), DIVES MED PRP TUBES (DVM1004), MAXXI PRP TUBES (MX1004), ATR PRP TUBES (ATR1004), PRPVET PRP TUBES (VT1004), GYNO-SHOT PRP TUBES (GSH1004), UNICELL PRP TUBES (UC 1004), PRIMA PRP TUBES (PR 1004), MIKADO PRP TUBES (MK 1004), TAILORED PRP TUBES (TL 1004), REMEDEX PRP TUBES (RM 1004)

T-LAB PRP TUBES (T1005), PRPHD PRP TUBES(HD1005), NEXT PRP TUBES (N1005), NATURALHAIR PRP TUBES (NHT1005), CLINICEXPERTLABS PRP TUBES (CEL1005), CELLHD PRP TUBES (C1005), PRPPROF TUBES (PP1005), PRPEXPERT TUBES (PE1005), XFACTOR PRP TUBES(X1005), YAVOPRP TUBES (Y1005), MEDEX PRP TUBES (M1005), INNMEDIS PRP TUBES (IN1005), ELITIN PRP TUBES (E1005), QUANTIX PRP TUBES (Q1005), AUTOSOMA PRP TUBES (A1005), ABALASE PRP TUBES (AB1005), OPUSS PRP TUBES (OP 1005), PROXELL PRP TUBES (PX 1005), PROGENİS PRP TUBES (PG 1005), GROWEX PRP TUBES (GR 1005), ARTHROPEX PRP TUBES (AR 1005), CUREVİTAL PRP TUBES (CU 1005), VİVERA PRP TUBES (VI 1005), RENEWEX PRP TUBES (RN 1005), REJUVERA PRP TUBES (RJ 1005), JOUVENCE PRP TUBES (JO 1005), PLASMOO PRP TUBES (PLO1005), DIVES MED PRP TUBES (DVM1005), MAXXI PRP TUBES (MX1005), ATR PRP TUBES (ATR1005), PRPVET PRP TUBES (VT1005), GYNO-SHOT PRP TUBES (GSH1005) UNICELL PRP TUBES (UC 1006), PRIMA PRP TUBES (PR 1005), MIKADO PRP TUBES (MK 1005), TAILORED PRP TUBES (TL 1005), REMEDEX PRP TUBES (RM 1005)

Product Description:	An autologous platelet rich plasma system for autologous soft and hard tissue including bone healing and intraarticular injections
Rule & Classification:	Rule 3 & Class IIb
GMDN:	47183
Basic UDI	8681092003PRPTUBESJM and 868275437PRPTUBES2B
Applied Directive:	The Directive 93/42/EEC on medical devices, conformity assessment according to Annex II (excluding section 4)
Applied Harmonized Standards:	ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2016, EN ISO 6710:2017, IEC 62366:2015, EN ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2010, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 11137-1:2018, EN ISO 11137-2:2015
Reference Guidance Documents:	MEDDEV 2.12/1 Rev 8, MEDDEV 2.12/2 Rev 2, MEDDEV 2.7/1 Rev.4, NB-MED/2.12/Rec.1, NBOG 2010-1
Notified Body:	Szutest Uygunluk Değerlendirme A.Ş. (NB2195)
Notified Body Address:	Tatlısu Mahallesi Akif İnan Sk. No:1 Ümraniye / Istanbul, TURKEY
EC Certificate:	2195-MED-1418102
EC Certificate Validity:	2024-04-25

The company T-BIYOTEKNOLOJI herewith declares that the above-mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all products of the above-mentioned type are safe and fulfil essential requirements of the 93/42/EEC Directive.

The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Place/Date of issue:

BURSA / TURKEY

15.12.2022

TİMUR VEYSEL DOĞRUOK

Digitally signed by TİMUR VEYSEL DOĞRUOK
Date: 2023.02.20 17:41:25 +03'00'

Timur V. DOĞRUOK – General Manager