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
Product:	PRX TUBES
Product Name:	T-LAB PRX TUBES (T2001), PRXHD TUBES (HD2001), NEXT PRX TUBES (N2001), NATURALHAIR PRX TUBES (NHT2001), CLINICEXPERTLABS PRX TUBES (CEL2001), CELLHD PRX TUBES (C2001), PRXPROF TUBES (PP2001), PRXPERT TUBES (PE2001), XFACTOR PRX TUBES (X2001), YAVOPRX TUBES (Y2001), MEDEX PRX TUBES (M2001), INNMEDIS PRX TUBES (IN2001), AUTOSOMA PRX TUBES (A2001), ABALASE PRX TUBES (AB2001), OPUSS PRX TUBES (OP2001), PROXELL PRX TUBES (PX2001), PROGENİS PRX TUBES (PG2001), GROWEX PRX TUBES (GR2001), ARTHROPEX PRX TUBES (AR2001), CUREVİTAL PRX TUBES (CU2001), VİVERA PRX TUBES (VI2001), RENEWEX PRX TUBES (RN2001), REJUVERA PRX TUBES (RJ2001), JOUVENCE PRX TUBES (JO2001), PLASMOO PRX TUBES (PLO2001), DIVES MED PRX TUBES (DVM2001), MAXXI PRX TUBES (MX2001), ATR PRX TUBES (ATR 2001), FILLASMA PRX TUBES (FL 2001), PRIMA PRX TUBES (PR 2001), MIKADO PRX TUBES (MK 2001), TAILORED PRX TUBES (TL 2001) T-LAB PRX TUBES (T2002), PRXHD TUBES (HD2002), NEXT PRX TUBES (N2002), NATURALHAIR PRX TUBES (NHT2002), CLINICEXPERTLABS PRX TUBES (CEL2002), CELLHD PRX TUBES (C2002), PRXPROF TUBES (PP2002), PRXPERT TUBES (PE2002), XFACTOR PRX TUBES (X2002), YAVOPRX TUBES (Y2002), MEDEX PRX TUBES (M2002), INNMEDIS PRX TUBES (IN2002), AUTOSOMA PRX TUBES (A2002), ABALASE PRX TUBES (AB2002), OPUSS PRX TUBES (OP2002), PROXELL PRX TUBES (PX2002), PROGENİS PRX TUBES (PG2002), GROWEX PRX TUBES (GR2002), ARTHROPEX PRX TUBES (AR2002), CUREVİTAL PRX TUBES (CU2002), VİVERA PRX TUBES (VI2002), RENEWEX PRX TUBES (RN2002), REJUVERA PRX TUBES (RJ2002), JOUVENCE PRX TUBES (JO2002), PLASMOO PRX TUBES (PLO2002), DIVES MED PRX TUBES (DVM2002), MAXXI PRX TUBES (MX2002), ATR PRX TUBES (ATR 2002), FILLASMA PRX TUBES (FL 2002), PRIMA PRX TUBES (PR 2001), MIKADO PRX TUBES (MK 2002), TAILORED PRX TUBES (TL 2002) T-LAB PRX TUBES (T2101), PRXHD TUBES (HD2101), NEXT PRX TUBES (N2101), NATURALHAIR PRX TUBES (NHT2101), CLINICEXPERTLABS PRX TUBES (CEL2101), CELLHD PRX TUBES (C2101), PRXPROF TUBES (PP2101), PRXPERT TUBES (PE2101), XFACTOR PRX TUBES (X2101), YAVOPRX TUBES (Y2101), MEDEX PRX TUBES (M2101), INNMEDIS PRX TUBES (IN2101), AUTOSOMA PRX TUBES (A2101), ABALASE PRX TUBES (AB2101), OPUSS PRX TUBES (OP2101), PROXELL PRX TUBES (PX2101), PROGENİS PRX TUBES (PG2101), GROWEX PRX TUBES (GR2101), ARTHROPEX PRX TUBES (AR2101), CUREVİTAL PRX TUBES (CU2101), VİVERA PRX TUBES (VI2101), RENEWEX PRX TUBES (RN2101), REJUVERA PRX TUBES (RJ2101), JOUVENCE PRX TUBES (JO2101), PLASMOO PRX TUBES (PLO2101), DIVES MED PRX TUBES (DVM2101), MAXXI PRX TUBES (MX2101), ATR PRX TUBES (ATR 2101), FILLASMA PRX TUBES (FL 2101), PRIMA PRX TUBES (PR 2101), MIKADO PRX TUBES (MK 2101), TAILORED PRX TUBES (TL 2101) T-LAB PRX TUBES (T2102), PRXHD TUBES (HD2102), NEXT PRX TUBES (N2102), NATURALHAIR PRX TUBES (NHT2102), CLINICEXPERTLABS PRX TUBES (CEL2102), CELLHD PRX TUBES (C2102), PRXPROF TUBES (PP2102), PRXPERT TUBES (PE2102), XFACTOR PRX TUBES (X2102), YAVOPRX TUBES (Y2102), MEDEX PRX TUBES (M2102), INNMEDIS PRX TUBES (IN2102), AUTOSOMA PRX TUBES (A2102), ABALASE PRX TUBES (AB2102), OPUSS PRX TUBES (OP2102), PROXELL PRX TUBES (PX2102), PROGENİS PRX TUBES (PG2102), GROWEX PRX TUBES (GR2102), ARTHROPEX PRX TUBES (AR2102), CUREVİTAL PRX TUBES (CU2102), VİVERA PRX TUBES (VI2102), RENEWEX PRX TUBES (RN2102), REJUVERA PRX TUBES (RJ2102), JOUVENCE PRX TUBES (JO2102), PLASMOO PRX TUBES (PLO2102), DIVES MED PRX TUBES (DVM2102), MAXXI PRX TUBES (MX2102), ATR PRX TUBES (ATR 2102), FILLASMA PRX TUBES (FL 2102), PRIMA PRX TUBES (PR 2102), MIKADO PRX TUBES (MK 2102), TAILORED PRX TUBES (TL 2102)
Product Description:	An autologous non-anticoagulated platelet rich plasma system for autologous soft and hard tissue including bone healing and intraarticular injections
Rule & Classification:	Rule 3 & Class IIa
GMDN:	47183
Basic UDI	8681092003PRXTUBESMV and 868275437PRXTUBES5K
Applied Directive:	The Directive 93/42/EEC on medical devices, conformity assessment according to Annex II (excluding section 4)
Applied Harmonized Standards:	ISO 13485, EN ISO 14971, EN 20417, EN ISO 15223-1, EN ISO 6710, IEC 62366, ISO 10993-1, EN ISO 10993-4, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-11, EN ISO 14644-1, EN ISO 14644-2, EN ISO 14644-3, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11607-1, EN ISO 11607-2, EN ISO 11137-1, EN ISO 11137-2
Notified Body:	Szutest Uygunluk Değerlendirme A.Ş. Notified Body Number 2195
EC Certificate:	2195-MED-1418102
Date of 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: 2023.03.27 10:18:37 +03'00'

Timur V. DOĞRUOK/General Manager

On Behalf of Company Co.