

EC Declaration of Conformity

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

Manufacturer: T-BIYOTEKNOLOJI LABORATUVAR ESTETİK MEDİKAL KOZMETİK SAN. VE TIC. LTD. STI.
Address: Dumlupınar Mahallesi, Kuleli Caddesi, No:3 Nilüfer/Bursa TÜRKİYE
Manufacturer ID No (SRN): TR-MF-000016403
Device Name: PRP TUBES

Ref No	Product	Ref No	Product	Ref No	Product
T1002	T-LAB PRP TUBES	VI 1002	VİVERA PRP TUBES	RNR1002	REONEER PRP TUBES
HD1002	PRPHD PRP TUBES	RN 1002	RENEWEX PRP TUBES	RX1002	REGX PRP TUBES
N1002	NEXT PRP TUBES	RJ 1002	REJUVERA PRP TUBES	VL1002	VALURE PRP TUBES
NHT1002	NATURALHAIR PRP TUBES	JO 1002	JOUVENCE PRP TUBES	CLT 1002	CELLITIUM PRP TUBES
CEL1002	CLINICEXPERTLABS PRP TUBES	PLO1002	PLASMOO PRP TUBES	BIO 1002	BIOTHINK PRP TUBES
C1002	CELLHD PRP TUBES	DVM1002	DIVES MED PRP TUBES	AD 1002	ADALINE PRP TUBES
PP1002	PRPPROF TUBES	MX 1002	MAXXI PRP TUBES	SRT 1002	SURGITEC PRP TUBES
PE1002	PRPEXPRT TUBES	ATR 1002	ATR PRP TUBES	ET 1002	EVOTERA PRP TUBES
X1002	XFACTOR PRP TUBES	GSH 1002	GYNO-SHOT PRP TUBES	PU 1002	PUREGEN PRP TUBES
Y1002	YAVOPRP TUBES	UC 1002	UNICELL PRP TUBES	IS 1002	INNOSTEM PRP TUBES
M1002	MEDEX PRP TUBES	PR 1002	PRIMA PRP TUBES	AUR 1002	AUREXA PRP TUBES
IN1002	INNMEDIS PRP TUBES	MK 1002	MIKADO PRP TUBES	CLA 1002	CLARIVITA PRP TUBES
E 1002	ELITIN PRP TUBE	TL 1002	TAILORED PRP TUBES	RD1002	REVODERM PRP TUBES
Q1002	QUANTIX PRP TUBES	RM 1002	REMEDEX PRP TUBES	DRM 1002	DERMAVIVAMED PRP TUBES
A1002	AUTOSOMA PRP TUBES	BC 1002	BIOCEN PRP TUBES	FFN 1002	FULL-FACE NATURAL PRP TUBES
AB1002	ABALASE PRP TUBES	DD 1002	D-MED PRP TUBES	SM 1002	SMARTFEM PRP TUBES
OP 1002	OPUSS PRP TUBES	EPB 1002	EP PRP TUBES	IC 1002	INOCURE PRP TUBES
PX 1002	PROXELL PRP TUBES	CX1002	CUREXA PRP TUBES	CLV 1002	CELOVITA PRP TUBES
PG 1002	PROGENİS PRP TUBES	GA1002	GENAURA PRP TUBES	PM 1002	PLASMORA PRP TUBES
GR 1002	GROWEX PRP TUBES	PLS1002	PELEUS PRP TUBES	EVO 1002	EVOLVEXA PRP TUBES
AR 1002	ARTHROPEX PRP TUBES	PV1002	PRIVATIS PRP TUBES	AL 1002	ALTHEVIA PRP TUBES
CU 1002	CUREVİTAL PRP TUBES	RC1002	REVIVOCELL PRP TUBES	GNR 1002	GENUREXA PRP TUBES
				IMD 1002	I+MED PRP TUBES

Brands:

Ref No	Product	Ref No	Product	Ref No	Product
T1003	T-LAB PRP TUBES	VI 1003	VİVERA PRP TUBES	RNR1003	REONEER PRP TUBES
HD1003	PRPHD PRP TUBES	RN 1003	RENEWEX PRP TUBES	RX1003	REGX PRP TUBES
N1003	NEXT PRP TUBES	RJ 1003	REJUVERA PRP TUBES	VL1003	VALURE PRP TUBES
NHT1003	NATURALHAIR PRP TUBES	JO 1003	JOUVENCE PRP TUBES	CLT 1003	CELLITIUM PRP TUBES
CEL1003	CLINICEXPERTLABS PRP TUBES	PLO1003	PLASMOO PRP TUBES	BIO 1003	BIOTHINK PRP TUBES
C1003	CELLHD PRP TUBES	DVM1003	DIVES MED PRP TUBES	AD 1003	ADALINE PRP TUBES
PP1003	PRPPROF TUBES	MX 1003	MAXXI PRP TUBES	SRT 1003	SURGITEC PRP TUBES
PE1003	PRPEXPRT TUBES	ATR 1003	ATR PRP TUBES	ET 1003	EVOTERA PRP TUBES
X1003	XFACTOR PRP TUBES	GSH 1003	GYNO-SHOT PRP TUBES	PU 1003	PUREGEN PRP TUBES
Y1003	YAVOPRP TUBES	UC 1003	UNICELL PRP TUBES	IS 1003	INNOSTEM PRP TUBES
M1003	MEDEX PRP TUBES	PR 1003	PRIMA PRP TUBES	AUR 1003	AUREXA PRP TUBES
IN1003	INNMEDIS PRP TUBES	MK 1003	MIKADO PRP TUBES	CLA 1003	CLARIVITA PRP TUBES
E 1003	ELITIN PRP TUBE	TL 1003	TAILORED PRP TUBES	RD1003	REVODERM PRP TUBES
Q1003	QUANTIX PRP TUBES	RM 1003	REMEDEX PRP TUBES	DRM 1003	DERMAVIVAMED PRP TUBES
A1003	AUTOSOMA PRP TUBES	BC 1003	BIOCEN PRP TUBES	FFN 1003	FULL-FACE NATURAL PRP TUBES
AB1003	ABALASE PRP TUBES	DD 1003	D-MED PRP TUBES	SM 1003	SMARTFEM PRP TUBES
OP 1003	OPUSS PRP TUBES	EPB 1003	EP PRP TUBES	IC 1003	INOCURE PRP TUBES
PX 1003	PROXELL PRP TUBES	CX1003	CUREXA PRP TUBES	CLV 1003	CELOVITA PRP TUBES
PG 1003	PROGENİS PRP TUBES	GA1003	GENAURA PRP TUBES	PM 1003	PLASMORA PRP TUBES
GR 1003	GROWEX PRP TUBES	PLS1003	PELEUS PRP TUBES	EVO 1003	EVOLVEXA PRP TUBES
AR 1003	ARTHROPEX PRP TUBES	PV1003	PRIVATIS PRP TUBES	AL 1003	ALTHEVIA PRP TUBES
CU 1003	CUREVİTAL PRP TUBES	RC1003	REVIVOCELL PRP TUBES	GNR 1003	GENUREXA PRP TUBES
				IMD 1003	I+MED PRP TUBES

Ref No	Product	Ref No	Product	Ref No	Product
TI004	T-LAB PRP TUBES	VI 1004	VIVERA PRP TUBES	RNR1004	REONEER PRP TUBES
HD1004	PRPHD PRP TUBES	RN 1004	RENEWEX PRP TUBES	RX1004	REGX PRP TUBES
N1004	NEXT PRP TUBES	RJ 1004	REJUVERA PRP TUBES	VL1004	VALURE PRP TUBES
NHT1004	NATURALHAIR PRP TUBES	JO 1004	JOUVENCE PRP TUBES	CLT 1004	CELLITIUM PRP TUBES
CEL1004	CLINICEXPERTLABS PRP TUBES	PLO1004	PLASMOO PRP TUBES	BIO 1004	BIOTHINK PRP TUBES
C1004	CELLHD PRP TUBES	DVM1004	DIVES MED PRP TUBES	AD 1004	ADALINE PRP TUBES
PP1004	PRPPROF TUBES	MX 1004	MAXXI PRP TUBES	SRT 1004	SURGITEC PRP TUBES
PE1004	PRPEXPRT TUBES	ATR 1004	ATR PRP TUBES	ET 1004	EVOTERA PRP TUBES
X1004	XFACTOR PRP TUBES	GSH 1004	GYNO-SHOT PRP TUBES	PU 1004	PUREGEN PRP TUBES
Y1004	YAVOPRP TUBES	UC 1004	UNICELL PRP TUBES	IS 1004	INNOSTEM PRP TUBES
M1004	MEDEX PRP TUBES	PR 1004	PRIMA PRP TUBES	AUR 1004	AUREXA PRP TUBES
IN1004	INNMEDIS PRP TUBES	MK 1004	MIKADO PRP TUBES	CLA 1004	CLARIVITA PRP TUBES
E 1004	ELITIN PRP TUBE	TL 1004	TAILORED PRP TUBES	RD1004	REVODERM PRP TUBES
Q1004	QUANTIX PRP TUBES	RM 1004	REMEDEX PRP TUBES	DRM 1004	DERMAVIVAMED PRP TUBES
A1004	AUTOSOMA PRP TUBES	BC 1004	BIOCEN PRP TUBES	FFN 1004	FULL-FACE NATURAL PRP TUBES
AB1004	ABALASE PRP TUBES	DD 1004	D-MED PRP TUBES	SM 1004	SMARTFEM PRP TUBES
OP 1004	OPUSS PRP TUBES	EPB 1004	EP PRP TUBES	IC 1004	INOCURE PRP TUBES
PX 1004	PROXELL PRP TUBES	CX1004	CUREXA PRP TUBES	CLV 1004	CELOVITA PRP TUBES
PG 1004	PROGENIS PRP TUBES	GA1004	GENAURA PRP TUBES	PM 1004	PLASMORA PRP TUBES
GR 1004	GROWEX PRP TUBES	PLS1004	PELEUS PRP TUBES	EVO 1004	EVOLVEXA PRP TUBES
AR 1004	ARTHROPEX PRP TUBES	PV1004	PRIVATIS PRP TUBES	AL 1004	ALTHEVIA PRP TUBES
CU 1004	CUREVITAL PRP TUBES	RC1004	REVIVOCELL PRP TUBES	GNR 1004	GENUREXA PRP TUBES
				IMD 1004	I-MED PRP TUBES

Ref No	Product	Ref No	Product	Ref No	Product
TI005	T-LAB PRP TUBES	VI 1005	VIVERA PRP TUBES	RNR1005	REONEER PRP TUBES
HD1005	PRPHD PRP TUBES	RN 1005	RENEWEX PRP TUBES	RX1005	REGX PRP TUBES
N1005	NEXT PRP TUBES	RJ 1005	REJUVERA PRP TUBES	VL1005	VALURE PRP TUBES
NHT1005	NATURALHAIR PRP TUBES	JO 1005	JOUVENCE PRP TUBES	CLT 1005	CELLITIUM PRP TUBES
CEL1005	CLINICEXPERTLABS PRP TUBES	PLO1005	PLASMOO PRP TUBES	BIO 1005	BIOTHINK PRP TUBES
C1005	CELLHD PRP TUBES	DVM1005	DIVES MED PRP TUBES	AD 1005	ADALINE PRP TUBES
PP1005	PRPPROF TUBES	MX 1005	MAXXI PRP TUBES	SRT 1005	SURGITEC PRP TUBES
PE1005	PRPEXPRT TUBES	ATR 1005	ATR PRP TUBES	ET 1005	EVOTERA PRP TUBES
X1005	XFACTOR PRP TUBES	GSH 1005	GYNO-SHOT PRP TUBES	PU 1005	PUREGEN PRP TUBES
Y1005	YAVOPRP TUBES	UC 1005	UNICELL PRP TUBES	IS 1005	INNOSTEM PRP TUBES
M1005	MEDEX PRP TUBES	PR 1005	PRIMA PRP TUBES	AUR 1005	AUREXA PRP TUBES
IN1005	INNMEDIS PRP TUBES	MK 1005	MIKADO PRP TUBES	CLA 1005	CLARIVITA PRP TUBES
E 1005	ELITIN PRP TUBE	TL 1005	TAILORED PRP TUBES	RD1005	REVODERM PRP TUBES
Q1005	QUANTIX PRP TUBES	RM 1005	REMEDEX PRP TUBES	DRM 1005	DERMAVIVAMED PRP TUBES
A1005	AUTOSOMA PRP TUBES	BC 1005	BIOCEN PRP TUBES	FFN 1005	FULL-FACE NATURAL PRP TUBES
AB1005	ABALASE PRP TUBES	DD 1005	D-MED PRP TUBES	SM 1005	SMARTFEM PRP TUBES
OP 1005	OPUSS PRP TUBES	EPB 1005	EP PRP TUBES	IC 1005	INOCURE PRP TUBES
PX 1005	PROXELL PRP TUBES	CX1005	CUREXA PRP TUBES	CLV 1005	CELOVITA PRP TUBES
PG 1005	PROGENIS PRP TUBES	GA1005	GENAURA PRP TUBES	PM 1005	PLASMORA PRP TUBES
GR 1005	GROWEX PRP TUBES	PLS1005	PELEUS PRP TUBES	EVO 1005	EVOLVEXA PRP TUBES
AR 1005	ARTHROPEX PRP TUBES	PV1005	PRIVATIS PRP TUBES	AL 1005	ALTHEVIA PRP TUBES
CU 1005	CUREVITAL PRP TUBES	RC1005	REVIVOCELL PRP TUBES	GNR 1005	GENUREXA PRP TUBES
				IMD 1005	I-MED PRP TUBES

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:

61377

EMDN:

V9099

Basic UDI

868275437PRPTUBES2B

Applied

Directive:

The Directive 93/42/EEC on medical devices, conformity assessment according to Annex II (excluding section 4)

Applied

Harmonized

ISO 13485:2016, EN ISO 14971:2019, ISO 24971:2020, EN ISO 20417:2021, EN ISO 15223-1:2021, EN ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-

D.0004 Release Date: 29.04.2019 / Revision Date: 27.11.2019 / 08.05.2020 / 06.10.2020 Rev. No:03 / 28.07.2021 Rev.04 / 25.08.2021 Rev.05/ 03.03.2022 REV06/ 09.05.2022 Rev.07/ 23.05.2022 Rev.08 / 03.06.2022 Rev.09 / 15.12.2022 Rev.10/ 21.03.2023 Rev.11 / 06.06.2023 R.12 / 19.12.2023 R.13/ 06.03.2024 Rev.14/ 25.04.2024 Rev.15/ 11.06.2024 Rev.16 / 19.09.2024 Rev 17(GMDN) / 24.04.2025 Rev18 (EMDN & SRN) / 17.06.2025 R19 (EPB) / 24.06.2025 R20 (8 Brands) / 10.09.2025 R21 (20 brands)

Standards

7:2008, EN ISO 10993-11:2017, EN ISO 10993- 18:2020, EN ISO 10993-23: 2021, EN ISO 10993-2: 2022, EN ISO 10993-10:2021, EN 62366-1:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2010, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11135:2014/A1:2019, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN 17141:2020, EN 556-1:2001/AC:2006, ISO 6710:2017, F1980:2016, ASTM F1929:2015, ASTM F88 F88M:2023, ASTM F 1886:2016, BS EN 868-5:2018

Reference

MEDDEV 2.7/1 rev.4, MEDDEV 2.12/1 rev.8, MEDDEV 2.12/2 Rev.2, MEDDEV 2.4-1 Rev.9, MDCG

Guidance

2018-1 Rev.4, MDCG 2019-9, MDCG 2020-3, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG

Documents:

2020-8, MDCG 2021-19, MDCG 2021-24, MDCG 2022-21

Notified Body:

Szutest Uygunluk Değerlendirme A.Ş. (NB2195)

Notified Body

Tatlısu Mahallesi Akif İnan Sk. No:1 Ümraniye / Istanbul, TURKEY

Address:**EC Certificate:**

2195-MED-1418102

EC Certificate

2024-04-25

Validity:

Extended Valid. Date:

31.12.2028

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

10.09.2025

IMMEDIIS