

## 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. STİ.

**Address:**

Dumlupınar Mahallesi, Kuleli Caddesi, No:3 Nilüfer/Bursa TÜRKİYE

**Product:**

PRX TUBES

Ref	Product	Ref	Product	Ref	Product
T2001	T-LAB PRX TUBES	RJ2001	REJUVERA PRX TUBES	RX2001	REGX PRX TUBES
HD2001	PRXHD TUBES	JO2001	JOUVENCE PRX TUBES	VL2001	VALURE PRX TUBES
N2001	NEXT PRX TUBES	PLO2001	PLASMOO PRX TUBES	E2001	ELITIN PRX TUBES
NHT2001	NATURALHAIR PRX TUBES	DVM2001	DIVES MED PRX TUBES	RM2001	REMEDEX PRX TUBES
CEL2001	CLINICEXPERTLABS PRX TUBES	MX2001	MAXXI PRX TUBES	CLT2001	CELLITIUM PRX TUBES
C2001	CELLHD PRX TUBES	ATR2001	ATR PRX TUBES	RD2001	REVODERM PRX TUBES
PP2001	PRXPROF TUBES	FL2001	FILLASMA PRX TUBES	BIO2001	BIOHINK PRX TUBES
PE2001	PRXPRT TUBES	PR 2001	PRIMA PRX TUBES	DRM2001	DERMAVIVAMED PRX TUBES
X2001	XFACTOR PRX TUBES	MK 2001	MIKADO PRX TUBES	AD2001	ADALINE PRX TUBES
Y2001	YAVOPRX TUBES	TL 2001	TAILORED PRX TUBES	FFN2001	FULL-FACE NATURAL PRX TUBES
M2001	MEDEX PRX TUBES	BC 2001	BIOCEN PRX TUBES	SRT2001	SURGITEC PRX TUBES
IN2001	INNMEDIS PRX TUBES	EM 2001	EXOMINE PRX TUBES	SM2001	SMARTFEM PRX TUBES
A2001	AUTOSOMA PRX TUBES	EV 2001	EXOVES PRX TUBES	ET2001	EVOTERA PRX TUBES
AB2001	ABALASE PRX TUBES	EP 2001	EXOPROF PRX TUBES	IC2001	INOCURE PRX TUBES
OP2001	OPUSS PRX TUBES	DD 2001	D-MED PRX TUBES	PU2001	PUREGEN PRX TUBES
PX2001	PROXELL PRX TUBES	EPB 2001	EP PRX TUBES	CLV2001	CELOVITA PRX TUBES
PG2001	PROGENİS PRX TUBES	CX2001	CUREXA PRX TUBES	IS2001	INNOSTEM PRX TUBES
GR2001	GROWEX PRX TUBES	GA2001	GENAURA PRX TUBES	PM2001	PLASMORA PRX TUBES
AR2001	ARTHROPEX PRX TUBES	PLS2001	PELEUS PRX TUBES	AUR2001	AUREXA PRX TUBES
CU2001	CUREVİTAL PRX TUBES	PV2001	PRIVATIS PRX TUBES	EVO2001	EVOLVEXA PRX TUBES
VI2001	VİVERA PRX TUBES	RC2001	REVIVOCCELL PRX TUBES	CLA2001	CLARIVITA PRX TUBES
RN2001	RENEWEX PRX TUBES	RNR2001	REONEER PRX TUBES	AL2001	ALTHEVIA PRX TUBES
GNR2001	GENUREXA PRX TUBES	REA2001	REONEER ADVANCED PRX TUBES	IMD2001	I+MED PRX TUBES
T2101	T-LAB PRX TUBES	RJ2101	REJUVERA PRX TUBES	RX2101	REGX PRX TUBES
HD2101	PRXHD TUBES	JO2101	JOUVENCE PRX TUBES	VL2101	VALURE PRX TUBES
N2101	NEXT PRX TUBES	PLO2101	PLASMOO PRX TUBES	E2101	ELITIN PRX TUBES
NHT2101	NATURALHAIR PRX TUBES	DVM2101	DIVES MED PRX TUBES	RM2101	REMEDEX PRX TUBES
CEL2101	CLINICEXPERTLABS PRX TUBES	MX2101	MAXXI PRX TUBES	CLT2101	CELLITIUM PRX TUBES
C2101	CELLHD PRX TUBES	ATR2101	ATR PRX TUBES	RD2101	REVODERM PRX TUBES
PP2101	PRXPROF TUBES	FL2101	FILLASMA PRX TUBES	BIO2101	BIOHINK PRX TUBES
PE2101	PRXPRT TUBES	PR 2101	PRIMA PRX TUBES	DRM2101	DERMAVIVAMED PRX TUBES
X2101	XFACTOR PRX TUBES	MK 2101	MIKADO PRX TUBES	AD2101	ADALINE PRX TUBES
Y2101	YAVOPRX TUBES	TL 2101	TAILORED PRX TUBES	FFN2101	FULL-FACE NATURAL PRX TUBES
M2101	MEDEX PRX TUBES	BC 2101	BIOCEN PRX TUBES	SRT2101	SURGITEC PRX TUBES
IN2101	INNMEDIS PRX TUBES	EM 2101	EXOMINE PRX TUBES	SM2101	SMARTFEM PRX TUBES
A2101	AUTOSOMA PRX TUBES	EV 2101	EXOVES PRX TUBES	ET2101	EVOTERA PRX TUBES
AB2101	ABALASE PRX TUBES	EP 2101	EXOPROF PRX TUBES	IC2101	INOCURE PRX TUBES
OP2101	OPUSS PRX TUBES	DD 2101	D-MED PRX TUBES	PU2101	PUREGEN PRX TUBES
PX2101	PROXELL PRX TUBES	EPB 2101	EP PRX TUBES	CLV2101	CELOVITA PRX TUBES
PG2101	PROGENİS PRX TUBES	CX2101	CUREXA PRX TUBES	IS2101	INNOSTEM PRX TUBES
GR2101	GROWEX PRX TUBES	GA2101	GENAURA PRX TUBES	PM2101	PLASMORA PRX TUBES

**Product Name:**

D.0005 Release Date: 12.12.2019

Revision Date:08.05.2020 Rev No:01 / 25.08.2021 Rev. No:2 / 21.04.2022 REV03/ 09.05.2022 Rev.04/ 23.05.2022 Rev.05/ 03.06.2022 Rev.06/ 15.12.2022 Rev.07 / 21.03.2023 Rev.08 / 19.12.2023 Rev.09 / 01.04.2024 Rev.10 / 25.04.2024 Rev.11 / 11.06.2024 Rev12 (address&brand)/ 19.09.204 Rev13 (GMDN) / 11.06.2025 (EMDN) R14 / R15 24.06.2025 / R16 10.03.2025 (23 brands)

AR2101	ARTHROPEX PRX TUBES	PLS2101	PELEUS PRX TUBES	AUR2101	AUREXA PRX TUBES
CU2101	CUREVITAL PRX TUBES	PV2101	PRIVATIS PRX TUBES	EVO2101	EVOLVEXA PRX TUBES
VI2101	VIVERA PRX TUBES	RC2101	REVIVOCELL PRX TUBES	CLA2101	CLARIVITA PRX TUBES
RN2101	RENEWEX PRX TUBES	RNR2101	REONEER PRX TUBES	AL2101	ALTHEVIA PRX TUBES
GNR2101	GENUREXA PRX TUBES	REA2101	REONEER ADVANCED PRX TUBES	IMD2101	I+MED PRX TUBES
T2002	T-LAB PRX TUBES	RJ2002	REJUVERA PRX TUBES	RX2002	REGX PRX TUBES
HD2002	PRXHD TUBES	JO2002	JOUVENCE PRX TUBES	VL2002	VALURE PRX TUBES
N2002	NEXT PRX TUBES	PLO2002	PLASMOO PRX TUBES	E2002	ELITIN PRX TUBES
NHT2002	NATURALHAIR PRX TUBES	DVM2002	DIVES MED PRX TUBES	RM2002	REMEDEX PRX TUBES
CEL2002	CLINICEXPERTLABS PRX TUBES	MX2002	MAXXI PRX TUBES	CLT2002	CELLITIUM PRX TUBES
C2002	CELLHD PRX TUBES	ATR2002	ATR PRX TUBES	RD2002	REVODERM PRX TUBES
PP2002	PRXPROF TUBES	FL2002	FILLASMA PRX TUBES	BIO2002	BIOHINK PRX TUBES
PE2002	PRXPRT TUBES	PR 2002	PRIMA PRX TUBES	DRM2002	DERMAVIVAMED PRX TUBES
X2002	XFACTOR PRX TUBES	MK 2002	MIKADO PRX TUBES	AD2002	ADALINE PRX TUBES
Y2002	YAVOPRX TUBES	TL 2002	TAILORED PRX TUBES	FFN2002	FULL-FACE NATURAL PRX TUBES
M2002	MEDEX PRX TUBES	BC 2002	BIOCEN PRX TUBES	SRT2002	SURGITEC PRX TUBES
IN2002	INNMEDIS PRX TUBES	EM 2002	EXOMINE PRX TUBES	SM2002	SMARTFEM PRX TUBES
A2002	AUTOSOMA PRX TUBES	EV 2002	EXOVES PRX TUBES	ET2002	EVOTERA PRX TUBES
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PX2002	PROXELL PRX TUBES	EPB 2002	EP PRX TUBES	CLV2002	CELOVITA PRX TUBES
PG2002	PROGENIS PRX TUBES	CX2002	CUREXA PRX TUBES	IS2002	INNOSTEM PRX TUBES
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CU2002	CUREVITAL PRX TUBES	PV2002	PRIVATIS PRX TUBES	EVO2002	EVOLVEXA PRX TUBES
VI2002	VIVERA PRX TUBES	RC2002	REVIVOCELL PRX TUBES	CLA2002	CLARIVITA PRX TUBES
RN2002	RENEWEX PRX TUBES	RNR2002	REONEER PRX TUBES	AL2002	ALTHEVIA PRX TUBES
GNR2002	GENUREXA PRX TUBES	REA2002	REONEER ADVANCED PRX TUBES	IMD2002	I+MED PRX TUBES
T2102	T-LAB PRX TUBES	RJ2102	REJUVERA PRX TUBES	RX2102	REGX PRX TUBES
HD2102	PRXHD TUBES	JO2102	JOUVENCE PRX TUBES	VL2102	VALURE PRX TUBES
N2102	NEXT PRX TUBES	PLO2102	PLASMOO PRX TUBES	E2102	ELITIN PRX TUBES
NHT2102	NATURALHAIR PRX TUBES	DVM2102	DIVES MED PRX TUBES	RM2102	REMEDEX PRX TUBES
CEL2102	CLINICEXPERTLABS PRX TUBES	MX2102	MAXXI PRX TUBES	CLT2102	CELLITIUM PRX TUBES
C2102	CELLHD PRX TUBES	ATR2102	ATR PRX TUBES	RD2102	REVODERM PRX TUBES
PP2102	PRXPROF TUBES	FL2102	FILLASMA PRX TUBES	BIO2102	BIOHINK PRX TUBES
PE2102	PRXPRT TUBES	PR 2102	PRIMA PRX TUBES	DRM2102	DERMAVIVAMED PRX TUBES
X2102	XFACTOR PRX TUBES	MK 2102	MIKADO PRX TUBES	AD2102	ADALINE PRX TUBES
Y2102	YAVOPRX TUBES	TL 2102	TAILORED PRX TUBES	FFN2102	FULL-FACE NATURAL PRX TUBES
M2102	MEDEX PRX TUBES	BC 2102	BIOCEN PRX TUBES	SRT2102	SURGITEC PRX TUBES
IN2102	INNMEDIS PRX TUBES	EM 2102	EXOMINE PRX TUBES	SM2102	SMARTFEM PRX TUBES
A2102	AUTOSOMA PRX TUBES	EV 2102	EXOVES PRX TUBES	ET2102	EVOTERA PRX TUBES
AB2102	ABALASE PRX TUBES	EP 2102	EXOPROF PRX TUBES	IC2102	INOCURE PRX TUBES
OP2102	OPUSS PRX TUBES	DD 2102	D-MED PRX TUBES	PU2102	PUREGEN PRX TUBES
PX2102	PROXELL PRX TUBES	EPB 2102	EP PRX TUBES	CLV2102	CELOVITA PRX TUBES
PG2102	PROGENIS PRX TUBES	CX2102	CUREXA PRX TUBES	IS2102	INNOSTEM PRX TUBES
GR2102	GROWEX PRX TUBES	GA2102	GENAURA PRX TUBES	PM2102	PLASMORA PRX TUBES
AR2102	ARTHROPEX PRX TUBES	PLS2102	PELEUS PRX TUBES	AUR2102	AUREXA PRX TUBES

D.0005 Release Date: 12.12.2019

Revision Date:08.05.2020 Rev No:01 / 25.08.2021 Rev. No:2 / 21.04.2022 REV03/ 09.05.2022 Rev.04/ 23.05.2022 Rev.05/ 03.06.2022 Rev.06/ 15.12.2022 Rev.07 / 21.03.2023 Rev.08 / 19.12.2023 Rev.09 / 01.04.2024 Rev.10 / 25.04.2024 Rev.11 / 11.06.2024 Rev12 (address&brand)/ 19.09.204 Rev13 (GMDN) / 11.06.2025 (EMDN) R14 / R15 24.06.2025 / R16 10.03.2025 (23 brands)

CU2102	CUREVITAL PRX TUBES	PV2102	PRIVATIS PRX TUBES	EVO2102	EVOLVEXA PRX TUBES
VI2102	VIVERA PRX TUBES	RC2102	REVIVOCELL PRX TUBES	CLA2102	CLARIVITA PRX TUBES
RN2102	RENEWEX PRX TUBES	RNR2102	REONEER PRX TUBES	AL2102	ALTHEVIA PRX TUBES
GNR2102	GENUREXA PRX TUBES	REA2102	REONEER ADVANCED PRX TUBES	IMD2102	I+MED PRX TUBES

**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:**

61377

**EMDN:** V9099

**Basic UDI**

868275437PRXTUBES5K

**Applied Directive:**

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

**Applied Harmonized Standards:**

EN 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 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-7:2008, 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 ISO 6710:2017, EN ISO 9626:2016, 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, F1980:2016, ASTM F1929:2015, ASTM F88 F88M:2023, ASTM F 1886:2016, BS EN 868-5:2018, 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 2018-1 Rev.4, MDCG 2019-9, MDCG 2020-3, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2021-19, MDCG 2021-24, MDCG 2022-21

**Notified Body:**

Szútest Ügyunluk Değerlendirme A.Ş.

Notified Body Number 2195

**EC Certificate:**

2195-MED-1418102

**Date of Validity:**

2024-04-25

**Extended Validity Date:**

31.12.2028

The company T-BIYOTEKNOLOJİ 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

Timur V. DOĞRUOK/CEO

**On Behalf of Company Co.**