

AT UYGUNLUK BEYANI

İMALATÇI : İSTEM MEDİKAL TIBBİ CİHAZ ve SAN. TİC. A.Ş.
ADRES : Anadolu OSB Mah. 29 Ekim Cad. No:41 Malıköy-Sincan Ankara/Türkiye
ÜRÜN : Steril Sodyum Hiyaluronat Jel
TİCARİ MARKA : Sensovisc, Artrosupp, Nevaflex, Regenvisc, OptiCore, Giasin, Cartiforce, EliteFlex, Riboline, Regenart, Flexgel, Sensoflex, So Matrix, Conramend, Synovialflex
MODELLER : Ekte verilmiştir.
GMDN : 44757
SINIFLANDIRMA : Sınıf III, Ek IX, Kural 8

UYGUNLUK DEĞERLENDİRME ROTASI: Ek 2 (Bölüm 4 dahil)

UYGULANABİLİR STANDARTLAR: EN ISO 13485:2016, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11135:2014, EN 285+A1:2021, EN ISO 17665-1:2006, EN ISO 14971:2020, ISO/TR 24971:2020, EN ISO 10993-1:2021, EN ISO 10993-2:2022, EN ISO 10993-3:2015, EN ISO 10993-4:2020, EN ISO 10993-5:2010, EN ISO 10993-6:2017, EN ISO 10993-7:2010, EN ISO 10993-10:2014, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-13:2011, EN ISO 15223-1:2021, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN 868-5:2019, EN ISO 19011:2018, EN ISO 7886-1:2018, EN ISO 80369-7:2021, EN ISO 20417:2021, EN ISO 17050-1:2010, EN ISO 17050-2:2005, EN 62366-1:2015, MDD 93/42 EEC, MDR 2017/745, MEDDEV 2.7/1 Rev 4:2016, MEDDEV 2.12/1 Rev 8:2013, MEDDEV 2.4/1 Rev 9:2010, MEDDEV 2.5/5 Rev 3:1998, MEDDEV 2.2/3 Rev3:1998, ASTM F 1980:2021, ASTM F88/F88M:2023, ASTM F1929:2023, EP 10, MDCG 2020-7, MDCG 2020-8, MDCG 2018-6, MDCG 2018-1 rev04, MDCG 2020-3, MDCG 2021-19, MDCG 2022-7, MDCG 2023-3, MDCG 2022-18, MDCG 2020-6, MDCG 2019-9, MDCG 2022-21, MDCG 2020-5.

Mevcut beyan kapsamındaki cihazın **93/42/AT Tıbbi Cihaz Direktifine, 2017/745 Tıbbi Cihaz Yönetmeliğine** ve varsa AB uygunluk beyanı düzenlenmesini sağlayan diğer ilgili Birlik mevzuatına uygun olduğunu beyan ederiz. Bu beyan, tamamen üreticinin sorumluluğu altında yayımlanmıştır. Destekleyici belgeler, imalatçının mülkiyeti altında tutulur.

ONAYLANMIŞ KURULUŞ: NB 2292-Udem Uluslararası Belgelendirme Denetim Eğitim Merkezi
San. ve Tic. A.Ş.
Adres: Mutlukent Mah. 2073 Sk. No:10 Çankaya – Ankara - TÜRKİYE

AT SERTİFİKA NUMARASI: M.2021.106.14528

TESCİL TARİHİ: 07.05.2021

GEÇERLİLİK TARİHİ: 27.05.2024

AT TASARIM İNCELEME SERTİKA NUMARASI: M.2021.106.14528-1

TESCİL TARİHİ: 07.05.2021

GEÇERLİLİK TARİHİ: 27.05.2024

Avrupa Parlamentosu ve Konseyi tarafından yayınlanan 2023/607 sayılı Yönetmelik kapsamında sertifikaların geçerlilik süresi Türkiye Sağlık ve İlaç Tıbbi Cihaz Kurumu tarafından **31/12/2027** tarihine kadar uzatılmıştır.

DÜZENLENME YERİ, TARİH: ANKARA, 23.05.2025

İMZA: LEVENT HAYYAOĞLU
GENEL MÜDÜR

NAZMIYE CUMALI
KALİTE GÜVENCE MÜDÜRÜ

İSTEM MEDİKAL
TIBBİ CİHAZ VE SAN. TİC. A.Ş.
Anadolu OSB Mah. 29 Ekim Cd. No:41 Malıköy
Sincan/ANKARA * Sincan V.D. 4811427978
Tel: 0312 394 55 62 * Fax: 0312 394 55 64

EC DECLARATION OF CONFORMITY

MANUFACTURER : İSTEM MEDİKAL TIBBİ CİHAZ ve SAN. TİC. A.Ş.
ADDRESS : Anadolu OSB Mah. 29 Ekim Cad. No:41 Malıköy-Sincan Ankara/Turkey
PRODUCT : Sterile Sodium Hyaluronate Gel
TRADE MARK : SensoVisc, ArtroSupp, NevaFlex, RegenVisc, Giasin, OptiCore, Cartiforce, EliteFlex, Riboline, So Matrix, Flexgel, Sensoflex, Rejenart, Synovialflex, Conramend
MODELS : It is given in Annex.
GMDN : 44757
CLASSIFICATION : Class III, Annex IX, Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex II (Including Section 4)

APPLICABLE STANDARDS: EN ISO 13485:2016, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11135:2014, EN 285+A1:2021, EN ISO 17665-1:2006, EN ISO 14971:2020, ISO/TR 24971:2020, EN ISO 10993-1:2021, EN ISO 10993-2:2022, EN ISO 10993-3:2015, EN ISO 10993-4:2020, EN ISO 10993-5:2010, EN ISO 10993-6:2017, EN ISO 10993-7:2010, EN ISO 10993-10:2014, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-13:2011, EN ISO 15223-1:2021, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN 868-5:2019, EN ISO 19011:2018, EN ISO 7886-1:2018, EN ISO 80369-7:2021, EN ISO 20417:2021, EN ISO 17050-1:2010, EN ISO 17050-2:2005, EN 62366-1:2015, MDD 93/42 EEC, MDR 2017/745, MEDDEV 2.7/1 Rev 4:2016, MEDDEV 2.12/1 Rev 8:2013, MEDDEV 2.4/1 Rev 9:2010, MEDDEV 2.5/5 Rev 3:1998, MEDDEV 2.2/3 Rev3:1998, ASTM F 1980:2021, ASTM F88/F88M:2023, ASTM F1929:2023, EP 10, MDCG 2020-7, MDCG 2020-8, MDCG 2018-6, MDCG 2018-1 rev04, MDCG 2020-3, MDCG 2021-19, MDCG 2022-7, MDCG 2023-3, MDCG 2022-18, MDCG 2020-6, MDCG 2019-9, MDCG 2022-21, MDCG 2020-5.

We herewith declare that the device that is covered by the present declaration is in conformity with **93/42/EEC Medical Device Directive, 2017/745 Medical Device Regulation** and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. This declaration is issued under the sole responsibility of the manufacturer. Supporting documentation is retained under the premises of the manufacturer.

NOTIFIED BODY: NB 2292-Udem Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Address: Mutlukent Mah. 2073 Sk. No:10 Çankaya – Ankara - TURKEY

EC CERTIFICATE NUMBER: M.2021.106.14528
REGISTRATION DATE: 07.05.2021

EXPIRY DATE: 27.05.2024

EC DESIGN EXAMINATION CERTIFICATE NUMBER: M.2021.106.14528-1
REGISTRATION DATE: 07.05.2021

EXPIRY DATE: 27.05.2024

Within the scope of the regulation 2023/607 published by the European Parliament and the Council, the validity period of the certificates has been extended by the Turkish Medicines and Medical Devices Agency until **31/12/2027**.

PLACE, DATE OF ISSUE : ANKARA, 23.05.2025

SIGNATURE: LEVENT HAYYAOĞLU

GENERAL MANAGER

İSTEM MEDİKAL
TIBBİ CİHAZ VE SAN. TİC. A.Ş.
Anadolu OSB Mah. 29 Ekim Cd. No:41 Malıköy
Sincan/ANKARA / Sincan V.D. 4811427978
Tel: 0312 394 55 64 * Fax: 0312 394 55 64

NAZMIYE CUMALI
QUALITY ASSURANCE MANAGER

MODELS

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
SENSOVISC	08699415730651	08699415730651	SV-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415730668	08699415730668	SV-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (%1.6)
	08699415730675	08699415730675	SV-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415730682	08699415730682	SV-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415730699	08699415730699	SV-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)
NEVAFLEX	08699415732532	08699415732532	NF-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415732549	08699415732549	NF-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (%1.6)
	08699415732556	08699415732556	NF-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415732563	08699415732563	NF-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415732570	08699415732570	NF-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)
OPTICORE	08699415733577	08699415733577	OC-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415733584	08699415733584	OC-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (%1.6)
	08699415733591	08699415733591	OC-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415733607	08699415733607	OC-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415733614	08699415733614	OC-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
REGENVISC	08699415732648	08699415732648	RV-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415732662	08699415732662	RV-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415732686	08699415732686	RV-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2.5)
ARTROSUPP	08699415732488	08699415732488	AS-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415732495	08699415732495	AS-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1.6)
	08699415732501	08699415732501	AS-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415732518	08699415732518	AS-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415732525	08699415732525	AS-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2.5)

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
GIASIN	08699415733676	08699415733676	GS-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(% 1)
Cartiforce	08699415733768	08699415733768	CF-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(% 1)
	08699415733775	08699415733775	CF-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415733782	08699415733782	CF-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(% 2)
	08699415733799	08699415733799	CF-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(% 2)
	08699415733805	08699415733805	CF-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (% 2.5)

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
EliteFlex	08699415733867	08699415733867	EF-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415733874	08699415733874	EF-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415733881	08699415733881	EF-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415733898	08699415733898	EF-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415733904	08699415733904	EF-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (% 2.5)
Riboline	08699415733812	08699415733812	RL-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415733829	08699415733829	RL-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415733836	08699415733836	RL-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415733843	08699415733843	RL-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415733850	08699415733850	RL-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (% 2.5)
Flexgel	08699415734093	08699415734093	FLX-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415734123	08699415734123	FLX-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(% 1.6)
	08699415738107	08699415738107	FLX-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415738114	08699415738114	FLX-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415738121	08699415738121	FLX-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2.5)

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
Sensoflex	08699415734093	08699415734093	SLX-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415734109	08699415734109	SLX-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415737070	08699415737070	SLX-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	086994157337087	086994157337087	SLX-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	086994157337094	086994157337094	SLX-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)
Rejenart	08699415734017	08699415734017	RA-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415734024	08699415734024	RA-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415734031	08699415734031	RA-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415734048	08699415734048	RA-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415734055	08699415734055	RA-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)
So Matrix	08699415733621	08699415733621	SM-2-20	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%1)
	08699415733638	08699415733638	SM-2-32	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe (% 1.6)
	08699415733645	08699415733645	SM-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415733652	08699415733652	SM-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2)
	08699415733669	08699415733669	SM-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)

Trade Name	UDI-DI		Ref No	Product Name
	Package	Box		
Conramend	08699415738152	08699415738152	CON-2-40	Sterile Sodium Hyaluronate Gel-2 ml Prefilled Syringe(%2)
	08699415738169	08699415738169	CON-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2)
	08699415738176	08699415738176	CON-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe(%2.5)
Synovialflex	08699415738213	08699415738213	VIA-3-60	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.0)
	08699415738220	08699415738220	VIA-3-75	Sterile Sodium Hyaluronate Gel-3 ml Prefilled Syringe (%2.5)