

## EC DECLARATION OF CONFORMITY

**MANUFACTURER :** İSTEM MEDİKAL TIBBİ CİHAZ ve SAN. TİC. LTD. ŞTİ.

**ADDRESS :** ANADOLU OSB MAH. 29 EKİM CAD. NO:41 MALİKÖY-SİNCAN/ANKARA  
TURKEY

**PRODUCT :** Sterile Lubricant Gel with Lidocaine (6 ml, 11ml prefilled gel in syringe and 12,5 g prefilled gel in accordion tube )

**MODEL :** It is given in the attached list.

**GMDN:** 60796

**CLASSIFICATION:** CLASS III, ANNEX-IX, RULE 5, RULE13

**CONFORMITY ASSESSMENT ROUTE:** ANNEX II (including section 4)

**APPLICABLE STANDARDS:** EN ISO 13485:2016, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN 868-2:2017, EN 868-3:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 14971:2019, EN ISO 10993-1:2021, EN ISO 10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-10:2014, EN ISO 15223-1:2016, EN ISO 19011:2018, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN ISO 14155:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 7886-1:2018, EN ISO 80369-7:2017, EN 980:2011, EN 1041:2008(A1:2014), EN ISO 17050-1:2013, EN ISO 17050-2:2007, TS EN 62366-1:2015, MDD 93/42 EEC, MEDDEV 2.7.1 Rev. 4:2016, MEDDEV 2.12-1 rev8:2013, MEDDEV 2.12-2 rev2:2012, MEDDEV 2.4/1:rev9:2010, MEDDEV 2.5/5:Rev 3:1998, ASTM F1980-16

**Pharmacopoeia monographs:** USP 35/Page 1191, EP 07/2010:0658, EP 09/2017 2.2.1-2.2.2, EP 09/2017 2.9.17, EP 09/2017 2.2.10, EP 09/2017 2.6.1, EP 09/2017:0409, EP 09/2017:0431

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND 2007/47/EC FOR MEDICAL DEVICES AND THESE PRODUCTS ARE NOT USED FOR MEDICINE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**NAME OF 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.2021.106.14615

**Registration Date:** 24.05.2021

**Expiry Date:** 27.05.2024

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**PLACE, DATE OF ISSUE:** ANKARA, 25.05.2021

**SIGNATURE:** LEVENT HAYYAOĞLU  
GENERAL MANAGER

**İSTEM MEDİKAL**  
TIBBİ CİHAZ ve SAN. TİC. LTD. ŞTİ.  
Anadoluh OSB MAH. 29 Ekim Cad  
No: 41 Maliköy Sincan / ANKARA  
Tel: (0312) 555 55 55 Fax: 394 55 64  
Sincan / B / 061 008 4741

NAZMİYE CUMALI  
QUALITY ASSURANCE MANAGER