EC DECLARATION OF CONFORMITY

MANUFACTURER : İSTEM MEDİKAL TIBBI CİHAZ ve SAN. TİC. LTD. ŞTİ.

ADDRESS : Anadolu OSB. Mah. 29 Ekim Cad. No: 41 Malıköy-Sincan Ankara-Turkey

PRODUCT : Sterile Injectable Implant for the treatment of Vesicoureteral Reflux (VUR)

TRADE MARK : DEXELL VUR

MODELS : DXL-5010

Ref No	UDI-DI	
	Single Package	Inner Box
DXL-5010	08698703339453	08698703339453

GMDN : 60700

CLASSIFICATION : Class III, Annex IX, Rule 8

CONFORMITY ASSESSMENT ROUTE: Annex 2 (Including Section 4)

APPLICABLE STANDARDS: EN ISO 13485:2016, EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 15223-1:2021, EN ISO 10993-1:2021, EN ISO10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-6:2017, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-16:2018, EN 868-3:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14937:2011, EN ISO 17665-1:2006, EN ISO 20417:2021, EN ISO 80369-7:2021, EN ISO 19011:2018, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN 285+A1:2021, EN ISO 7886-1:2018, EN ISO 17050-1:2010, EN ISO 17050-2:2005, EN 62366-1:2015, MEDDEV 2.7.1 REV4:2016, MEDDEV 2.12/1 REV8:2013, MEDDEV 2.4/1 REV9:2010, MEDDEV 2.5/5 REV3:1998, MEDDEV 2.2/3 Rev3:1998, ASTM F 1980:2021, ASTM F1929:2015, ASTM F88/F88M:2021, EP10:2019, 93/42/EEC MDD, 2017/745 MDR, MDCG 2020-7, MDCG 2020-8, MDCG 2018-6, MDCG 2018-1 rev04, MDCG 2020-3 rev01, MDCG 2021-19, MDCG 2022-7, MDCG 2022-18, MDCG 2022-21, EU 2023/607.

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. All supporting documentation is retained under the premises of the manufacturer.

NAME OF NOTIFIED BODY: NB 2292 - UDEM Uluslararasi Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Address: Mutlukent Mahallesi 2073 Sokak No:10 CANKAYA/ANKARA/TURKEY

EC CERTIFICATE NUMBER: M.2021.106.14286
Registration Date: 10.02.2021 **Expiry Date:** 08.03.2022

EC DESIGN EXAMINATION CERTIFICATE NUMBER: M.2021.106.14286-1
Registration Date: 10.02.2021 **Expiry Date:** 08.03.2022

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

PLACE, DATE OF ISSUE : ANKARA, 26.05.2023
SIGNATURE:
LEVENT HAYYAOĞLU
GENERAL MANAGER

NAZMİYE CUMALI
QUALITY ASSURANCE MANAGER

İSTEM MEDİKAL
Tıbbi Cihaz ve San.Tic.Ltd.Şti.
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