EC DECLARATION OF CONFORMITY

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

ADDRESS : Anadolu OSB. Mah. 29 Ekim Cad. No: 41 Malıköy-Sincan Ankara-Turkey
Tel: +90 312 394 55 62, **e-mail:** istem@istemmedikal.com

PRODUCT : Sterile Injectable Implant for Vesicoureteral Reflux (VUR)

TRADE MARK : DEXELL VUR

MODEL : DXL-5010

BARCODE : 8698703339453

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 15223-1:2016, EN ISO 10993-1:2018, EN ISO10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-6:2017, EN ISO 10993-10:2014, EN ISO 10993-11:2018, EN ISO 10993-12:2013, EN ISO 10993-16:2018, EN 556-1:2009, 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 17141:2020, EN ISO 14937:2011, EN ISO 17665-1:2006, EN 1041:2008 (A1:2014), EN ISO 80369-7:2017, EN ISO 19011:2018, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2019, EN 285:2016, 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 2.12/2 REV2:2012, MEDDEV 2.2/3 Rev3:1998, ASTM F 1980-16:2016, EP09:2017

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
Address: Mutlukent Mahallesi 2073 Sokak No:10 Ümitköy-CANKAYA/ANKARA/TURKEY
Tel No: 00 90 312 443 03 90

EC CERTIFICATE NUMBER: M.2021.106.14286
Certificate Date: 10.02.2021 **Valid until:** 08.03.2022

EC DESIGN EXAMINATION CERTIFICATE NUMBER: M.2021.106.14286-1
Certificate Date: 10.02.2021 **Valid until:** 08.03.2022

PLACE, DATE OF ISSUE : ANKARA, 10.02.2021

SIGNATURE : LEVENT HAYYAOĞLU
GENERAL MANAGER

İSTEM MEDİKAL TIBBİ CİHAZ VE SAN.TİC.LTD.ŞTİ.
Anadolu OSB. Mah. 29 Ekim Cad. No:29 Malıköy/Sincan/ ANKARA
Tel: 0312 394 55 62 Fax : 394 55 64
ŞUBE: İSTEM MEDİKAL TIBBİ CİHAZ VE SAN.TİC.LTD.ŞTİ. MALIKÖY OSB. ŞUBESİ
Anadolu OSB. Mah. 29 Ekim Cad. No: 41 Sincan/Ankara
SİNCAN V.D. 481 008 4741 Mersis No:0481008474100032

NAZMİYE CUMALI
QA MANAGER