EC DECLARATION OF CONFORMITY

MANUFACTURER :İSTEM MEDİKAL TIBBI CİHAZ VE SAN.LTD. ŞTİ.
ADDRESS : Anadolu OSB. Mah. 29Ekim Cad. No: 39 Malıköy-Sincan ANKARA/TURKEY

TEL: +90 312 394 55 62-63 FAKS: +90 312 394 55 64

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

MODELS: DXL-5010

GMDN: 60700

CLASSIFICATION: CLASS III,

CONFORMITY ASSESSMENT ACCORDING TO 93/42/EEC: ANNEX 2, SECTION 3,4, RULE 8

APPLICABLE STANDARDS :
EN ISO 13485:2012, EN ISO 13485:2016, EN ISO 9001:2008, EN ISO 9001:2015, EN ISO 14971:2013, EN ISO 15223-1:2013, EN ISO 10993-1:2011, EN ISO10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-6:2010, EN ISO 10993-10:2014, EN ISO 10993-11:2010, EN ISO 10993-16:2010, EN 556-1:2009 , EN 868-3:2010, EN ISO 11737-1:2006, EN ISO 11737-2:2010, EN ISO 11607-1:2010, EN ISO 11607-2:2010, EN ISO 14698-1:2014, EN ISO 14937:2011, EN ISO 17665-1:2014, EN 1041+A1:2014, TS 3521-2 EN 1707:2001, EN ISO 19011:2012, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2006, EN ISO 14155:2012, EN 285:2016, ASTM F 1980-07:2011, ASTM F 1980-07 :2011

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 1783 - TURKISH STANDARDS INSTITUTION (TSE)**

EC CERTIFICATE NUMBER : 1783-MDD-038 **Valid until:** 08.03.2022

EC Design Examination Certificate Number: 1783-MDD-039 **Valid until:** 08.03.2022

PLACE, DATE OF ISSUE :ANKARA, 08.03.2017

SIGNATURE : LEVENT HAYYAOĞLU
GENERAL MANAGER

İSTEM MEDİKAL
TIBBI CİHAZ ve SAN TİC LTD ŞTİ
Anadolu OSB Mah 29 Ekim Cad.
No 39 Malıköy Sincan ANK
Tel:(0.312) 394 55 62-63 Fax 394 55 64
Polatlı V D 481 008 4741

DURDANE KALENDER
QUALITY ASSURANCE MANAGER