

EC DECLARATION OF CONFORMITY

KLAS MEDİKAL CİHAZLAR SANAYİ MÜESSİLLİK İÇ VE DİŞ TİC LTD.ŞTİ
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Product : **SURGICAL INCISE DRAPE**
Classification : **Class Is Rule 1**
Brand : **HITEC**
GMDN Code : **47783**

Applicable Directive and Standards:

Medical Devices Directive (MDD) 93/42/EEC + 2007/47/EC

Medical Device Regulation EU 2017/745(Article 120)+ Regulation(EU)2023/607

EN ISO 13485:2016+A11:2021	EN ISO 14937:2009	ASTM D3654-2019
EN ISO 11135:2014+A1:2019	EN ISO 14644-1:2015	EN ISO 14644-2:2015
EN ISO 14644-3:2019	EN ISO 20417:2021	EN ISO 15223-1:2021
EN ISO 14971:2019+A11:2021	EN ISO 10993-1:2020	EN ISO 10993-5:2009
EN ISO 10993-7:2008+A1:2022	EN ISO 10993-10:2021	EN ISO 11737-1:2018 +A1:2021
EN ISO 11737-2:2020	ASTM F 1980-2021	ASTM F 1929-2015
EN ISO 11607-1:2020+A11:2022	EN ISO 11607-2:2020+A11:2022	EN 17141:2020
EN ISO 22610:2006	EN ISO 22612:2005	TS 3957:2018
ISO/TR 20416:2020	EN ISO 20645:2004	MDCG 2020-3 Rev.1
MDCG 2020-7	MDCG 2020-8	MDCG 2019-7
MDCG 2021-1 Rev1	GHFT-SG2/N54R8:2006	

Method of Conformity Assessment: Annex 2 (excluding section 4)

REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)
D1010	DU1010	10x10	D3030	DU3030	30x30	D4540	DU4540	45x40	D6045	DU6045	60x45
D1012	DU1012	10x12	D3035	DU3035	30x35	D4545	DU4545	45x45	D6050	DU6050	60x50
D1020	DU1020	10x20	D3040	DU3040	30x40	D4548	DU4548	45x48	D6055	DU6055	60x55



INFUSION SET WITH NEEDLELESS ADAPTERS



Features

- Eliminates retrograde fluid up the IV line
- Designed for general I.V. Therapy, Anesthesia Cardiovascular & CCU, Recovery & Oncology
- Safe for infusion IV medication including most high risk anti-plastic, or aspirating blood without risk of hemolysis

Product No.	Description
41.05.20003	One way
41.05.20002	Two way
41.05.20001	Three way
41.05.30001	Y type with filter

(1) Infusion set with needleless adapters (for adults):

- Eliminates retrograde fluid up the Iv line
- Designed for general I.v. Therapy, Anesthesia Cardiovascular, ICU & CCU, Recovery & Oncology
- Safe for infusion Iv medication including most high risk anti-neo-plastic, or aspirating blood without risk of hemolysis