biotex	**Declaration Of Conformity**	Document No	TF.01.02
		Revision No	00
		Revision Date	-
		Issue Date	7.03.2022
		Page	Sayfa 1 of 3

Legal Manufacturer Name	**BİOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SAN.VE TİC A.Ş**
SRN Number	**TR-MF-000023145**
Legal Manufacturer Address	İslampaşa Mh. 2 Nolu Şehitler Cd. No:41/G MERKEZ RİZE
Risk Class	Class IS
Rule	Rule I
Confotmity Assessment Route	Annex IX - Parts I and II - Conformity assessment based on the Quality management system and on assessment of the technical documentation
Device Name	Sterile Disposable Surgical Drapes, Gowns and Sets
Basic UDI-DI	8681881208TD01HS
Notified Body	Kiwa Cermet Italia NB0476 Via Cadriano, 23, 40057 Granarolo dell'Emilia BO, Italy
EC Certificate No:	
Certificate Revision No and Issue Date:	
Certificate Expiration Date:	

This EU declaration of conformity is issued under the sole responsibility of the legal manufacturer.

The device that is covered by the present declaration is in conformity with this 2017/745 Medical Device Regulation.

The device list is defined in the list with document code TF.01.02.01.

The device description is presented as an additional document together with the declaration of conformity.

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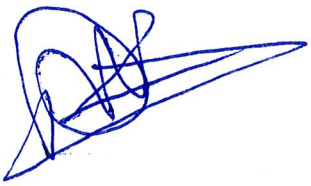
		Page	Sayfa 1 of 3

Applied Standards:

EN ISO 14971: 2019, EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 11135:2014, EN ISO 13795-1:2019, Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC, Medical Device Directive Annex II, 2017/745 MDR Medical Device Regulation

Rev. No	Rev. Date	Revision History
00	.....	The first publish according to MDR.
Authorized Personnel		**Place / Date**
Ertan Demir		Rize / 18.10.2022



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Magdalena Włodek
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