

EU DECLARATION OF CONFORMITY

REAL MEDİKAL TIBBİ GEREÇLER İNŞ. TAAH. GIDA MOB. TURİZM SAN. TİC. LTD. ŞTİ.

This declaration of conformity is issued under the sole responsibility of the manufacturer

1	Manufacturer	REAL MEDİKAL Tıbbi Gereçler İnş. Taah. Gıda Mob. Turizm San. Tic. Ltd. Şti.	
2	Address	Center Office	Mevlana Bulvarı No: 182/B-52 Postcode:06000 Çankaya / Ankara TURKEY
		Production/Factory	Adres: Çukurova mahallesi 228. Cadde N:97/BD Toroslar/ Mersin TURKEY
3	Product name	Surgical Gown	
4	Model / Serial No	RAC 25-1	
5	Technical Reference	BSI's PPE Technical Specification for Healthcare Professionals during the Covid-19 Pandemic 2020/403	
6	Applicable Regulation	PPE Regulation 2016/425 (Cat. III PPE) & Medical Device Regulation 2017/745 EEC (Class I, non-sterile).	
7	Harmonised Standards	Performance as tested in accordance with Clauses 4.1, 4.2.1 and 4.2.2 of EN 13034:2005+A1:2009, met the requirements of Type PB(6) and Clauses 4.1.4.1 of EN 14126:2003, ISO 16604:2004 Resistance to penetration by blood borne pathogens EN ISO 13688:2013, EN 14325:2014, ISO 17491-4:2008 and ISO 13485:2016.	
8	Notified Body for EU type-examination (Module B)	BSI Group - NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands	
9	Certificate number	B Modül CE 732522	
10	Notified Body for EU type-examination (Module C2)	BSI Group NB 2797 The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands	
11	Certificate number	C2 Modül CE 732524	
12	Reference No	2375	

We declare that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

Product Name	GMDN Code	Reference Code
Disposable Gowns, Non-Sterile		
Laminated Surgical Gown, Size S	35092	25.001.01
Laminated Surgical Gown, Size M		25.001.02
Laminated Surgical Gown, Size L		25.001.03
Laminated Surgical Gown, Size XL		25.001.04
Laminated Surgical Gown, Size XXL		25.001.05
Laminated Surgical Gown, Size XXXL		25.001.06

Signed for and on behalf of:

REAL MEDİKAL

Tıbbi Gereçler İnş. Taah. Gıda Mob.
Turizm San. Tic. Ltd. Şti.

21.12.2020

REAL MEDİKAL
TIBBİ GEREÇLER İNŞ. TAAH. GIDA
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