EC Declaration of Conformity

issued in accordance with EC directive 98/79/EC relating to Medical Devices

Manufacturer:	RED CELL BİYOTEKNOLOJİ A.Ş.
Adress:	ŞERİFALİ MAHALLESİ BEYİT SOKAK NO:66/4 ÜMRANİYE/İSTANBUL
Product name:	REDCELL COVID 19 DIAGNOSTIC SYSTEMS
Product models:	

COVID-19 Antigen Test

Product description:	COVID 19 DIAGNOSTIC SYSTEMS PRODUCTION
Applied directives:	The Directive 98/79/EC on medical devices, conformity assessment according to Annex III
Classification:	IVD Others
Applied harmonized standards:	EN ISO 14971:2012, EN ISO 15223-1 : 2016, EN ISO 13485:2016, BS EN 13612:2002/AC:2002, BS EN ISO 23640:2015, ISO 18113-1:2009, ISO 18113-2:2009,

The company REDCELL here with declares that the above-mentioned product meets all applicable provisions of the Directive 98/79/EC. The products are safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all products of the above mentioned type are safe and fulfill essential requirements of the 98/79/EC Directive.

The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 29th, January, 2021

Dr. Erdal ATAC, President

On Behalf of Company Co.

RED CELL BİYOTEKNOLOJİ ANONİM ŞİRKETİ
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