SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ.

CE-DOC-OG216
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Spesera Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.*

Legal Manufacturer Address: *Göztepe mah. Batışehir cad. No:2/3 İç Kapı No:1B12 Bağcılar/İSTANBUL-TURKEY*

Declares, that the products
Product Name and Model(s)

HbsAg Rapid Test Cassette	SP-216

Classification: *Other*
Conformity assessment route: *Annex III Applied (IVD 98/79/EC)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

The following standards were used to prove conformity:
-EN ISO13485:2016
-EN ISO9001:2015

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: July 22, 2020

Name of authorized signatory:
Abdulhamit ASSAF

Digitally signed by Chirtoacă Iurie
Date: 2021.09.21 10:33:49 EEST
Reason: MoldSign Signature
Location: Moldova