



THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 163897

Date of Issue : 17 September 2021

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ TİC. LTD. ŞTİ." (Göztepe Mh. Batışehir Cd. No:2/3/1b12 BAĞCILAR İSTANBUL), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Turkey.

This certificate is issued to be given to the relevant competent authorities of "Bulgaria" and is valid for 36 months from the date of issue.

Yours sincerely,


Ömer Faruk KURU
Head of Medical Devices
Registration and Coordination Department

This certificate consists of 4 page/s and 22 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through

<https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele>.



PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8681176311002	SPESERA	COVID-19 IgG/IgM Rapid Test Cassette	SP-225	64756
2	8681176311019	SPESERA	sNAT Transfer Tube	SP-227	58697
3	8681176311026	SPESERA	SPESERA COVID - 19 Antigen Rapid Test Cassette	SP-226	64787
4	8681176311125	SPESERA	Influenza A+B Rapid Test Cassette	SP-222	49119
5	8681176311156	SPESERA	H.PYLORI ANTIGEN Rapid Test Cassette	SP-207	30825
6	8681176311354	SPESERA	FOB Rapid Test Cassette	SP-304	54532
7	8681176311385	SPESERA	HAV IgG/IgM Rapid Test Cassette	SP-215	48270
8	8681176311064	SPESERA	TROPONIN I Rapid Test Cassette	SP-306	46989
9	8681176311095	SPESERA	CHLAMYDIA Rapid Test Cassette	SP-109	50759
10	8681176311101	SPESERA	CK-MB Rapid Test Cassette	SP-307	52995



Date of Issue : 17 September 2021

11	8681176311088	SPESERA	BETA HCG (PREGNANCY) Rapid Test Cassette	SP-103	33819
12	8681176311132	SPESERA	Beta HCG DİPSTİCK	SP-101	33819
13	8681176311149	SPESERA	Urine Strip 10T	SP-309	54514
14	8681176311187	SPESERA	SYPHILIS Rapid Test Cassette	SP-219	51788
15	8681176311194	SPESERA	GIARDİA LAMBİA Rapid Test Cassette	SP-205	52249
16	8681176311248	SPESERA	H.PYLORI ANTIBODY Rapid Test Cassette	SP-206	62029
17	8681176311231	SPESERA	STREP A HIZLI TEST	SP-220	51707
18	8681176311224	SPESERA	DENGUE IgG/IgM Rapid Test Cassette	SP-208	63238
19	8681176311200	SPESERA	TYPHOID Rapid Test Cassette	SP-211	51560
20	8681176311347	SPESERA	TUBERCULOSIS (TB) Rapid Test Cassette	SP-223	51172
21	8681176311279	SPESERA	ADENOVİRÜS Rapid Test Cassette	SP-201	49856



Date of Issue : 17 September 2021

22	8681176311170	SPESERA	ROTAVİRÜS- ADENOVİRÜS Rapid Test Cassette	SP-204	48235
----	---------------	---------	--	--------	-------

End of product schedule.

