



Notified Body No.1023
INSTITUT FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic - www.itczlin.cz

EC Desing-Examination Certificate No. 19 0386 CN/NB

Issued in compliance with Council Directive 98/79/EC on in vitro diagnostic medical devices as amended, the requirements of which are implemented by the Czech Government Order No. 453/2004 Collection of laws, for the product.

Pregnancy Test

brand name. **BORK & JASO Pregnancy Test, BORK & JASO Ovulation Test, BORK & JASO Early Pregnancy Test**

manufactured by the company

Oben Ilaç Medikal Kozmetik Dış Tic. Ltd. Şti.
Oruçreis Mah. Giyimkent 3.Sok. No:61/A Esenler – Istanbul – Turkey

The Notified Body No. 1023 has conducted the Design examination of the above product and certifies that the requirements of Annex III, article 6 of the aforementioned directive have been met. The product description and details on the examination procedure are presented in the Final Reports No. 813600752/2019, which is enclosed to this Certificate.

The Certificate remains valid until any significant change to the approved design of the above mentioned products is made but until 16th December 2024 at the latest.

Conditions of use of this Certificate and related information:

1. *This Certificate is issued on a voluntary basis and is valid only in relation to the product(s) and its modifications shown on the Certificate and in relation to the issued certification document.*
2. *Institut pro testování a certifikaci, a.s., the issuer of this Certificate, confirms the existence of relevant certification document.*
3. *This Certificate does not suggest in any way that supervision or control of production was carried out by ITC.*
4. *This certificate remains valid unless there is a change in the production technology or in the relevant standards or regulations, but not longer than specified below.*
5. *The holder of this Certificate is obliged to organize their own system of production quality assurance so that the certified product complies with the requirements specified by the certification document and terms of use of this certificate permanently for the entire validity of this Certificate, and shall notify ITC of any change in raw materials or production technologies which could affect the characteristics of the certified product.*
6. *When using the Certificate, the holder of this Certificate shall comply with the Rules for certificate use publicly available on www.itczlin.cz.*
7. *The validity of the Certificate can be verified on www.itczlin.cz.*

CE 1023



Paul Vaj
RNDr. Radomír Čevelík

Representative of the Notified Body No.1023

Issued in Zlin, on 16th December 2019